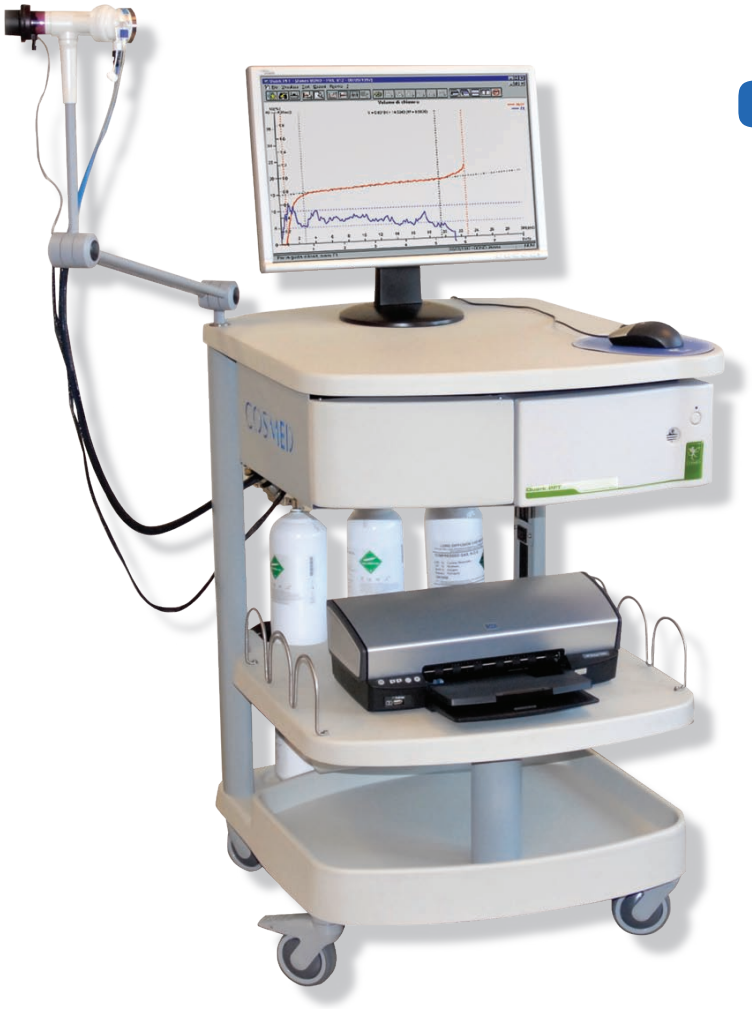
Quark PFT
Quark CPET
Quark SPIRO



Manuale Utente

User Manual

Manuel d'utilisation

Benutzerhandbuch

Manual del Usuario

COSMED
Pulmonary Function Equipment

Quark User manual, XI Edition

06/2013

COSMED Srl - Italy

http://www.cosmed.com

Part N. C03262-02-91

Table of contents

Getting started

Important notices

Intended use

The COSMED Quark Series system is a modular system with multiple configurations, allowing the following measurements: Spirometry, Lung Function Testing, Cardiopulmonary Exercise Testing, Resting Metabolism.

The system and its accessories are indicated for the acquisition, analysis, formatting, display, printing and storage of certain physiologic signals. It is intended to assist a clinician in the diagnosis of cardio-pulmonary disease conditions.

Caution: Federal law restricts this device to be sold by the order of a physician.

The device must not be intended as a monitoring device, nor as a sole means for determining a patients diagnosis but for the purpose of assisting the clinician in the diagnosis of cardio-pulmonary diseases.

This equipment is intended to be used for the following applications:

- Formulating of a lung pathology diagnosis.
- Assisting with human physiology studies.
- Contributing to sports medicine applications.

COSMED Srl is not responsible for incidents which occur due to improper use of this device. Examples include:

- Operation of the device by unqualified individuals.
- Use of the device not indicated by this manual.
- Not complying with the precautions and instructions described in this manual.

Specific Indications for use

Device model	Indication for use	Major clinical conditions	Measured parameters
Quark SPIRO	Pulmonary Function testing - Age 6 to adults	Spontaneously breathing patients, healthy or affected by respiratory diseases such as asthma or COPD	FVC, FEV1, FEF25-75%, PEF, MVV, SpO_2
Quark PFT	Pulmonary Function testing - Age 6 to adults Cardiopulmonary Exercise testing – age 6 to adults	Spontaneously breathing patients, healthy or affected by respiratory diseases such as asthma or COPD	FVC, FEV1, FEF25-75%, PEF, MVV, FRC, DLCO, MIP/MEP, P0.1, SpO_2, Ve, RF, HR, VO_2, VCO_2, TGV
Quark CPET	Pulmonary Function testing - Age 6 to adults Cardiopulmonary Exercise testing – age 6 to adults	Spontaneously breathing patients, healthy or affected by diseases limiting exercise tolerance	FVC, FEV1, FEF25-75%, PEF, MVV, VO_2, VCO_2, Ve, RF, HR, SpO_2

Quark SPIRO and Quark PFT also allows the Airways Resistance Test through the interruption technique (R_{OCC} test) for young patients from 3 to 6 years old. R_{OCC} technique was specifically developed for young, non cooperative children, not able to perform the spirometric maneuvers. The interrupter technique is feasible and repeatable in preschool children, has a good correlation with “gold standard” techniques, and is able to detect changes in airway caliber.

Description of the acronyms used in measured parameters

Parameter	Description
FVC	Forced Expiratory Vital Capacity
FEV1	Forced Expiratory Volume in 1 sec
FEF25-75%	Mid-expiratory flow between 25-75% of the FVC
PEF	Peak Expiratory Flow
MVV	Maximum Voluntary Ventilation
FRC	Functional Residual Capacity

Parameter	Description
P0.1	Respiratory Drive
Ve	Ventilation
RF	Respiratory frequency
HR	Heart Rate
VO_2	Oxygen uptake
VCO_2	Carbon Dioxide production

DLCO	CO Diffusion Capacity
MIP	Maximum inspiratory pressure
MEP	Maximum expiratory pressure

SpO_2	Hemoglobin saturation
TGV	Thoracic Gas Volume

Warnings

The device, program algorithms and presentation of the measured data has been developed in accordance with the specifications outlined by the ATS (American Thoracic Society) and ERS (European Respiratory Society). Additional international references have also been applied where applicable. All bibliography references are reported in the Appendix.

This User Manual has been developed in accordance with the Class IIa European Medical Device Directive requirements.

> ***Warning:*** *To avoid risk of electric shocks, this device must be connected to sockets with protective earth.*

The precautions listed below should be noted before operating the device to ensure the safety of the user.

1. This User Manual should always be available as a reference when testing.
2. The following standards should be applied to ensure the accuracy of individual test results:
   - Accessories should only be used as described in this manual. The manufacturer does not warranty any non-authorized accessories used by the end user. The manufacturer may offer suggestions while using such accessories and the complications they could cause;
   - Repairs or modifications of the device should ONLY be carried out by qualified and trained personnel;
   - Environmental and electrical conditions in which the device operates should be in compliance with the specifications of this manual. In particular grounding reliability and leakage current suppression can only be assured when the device three-wire receptacle is connected to a yellow-green return connected to earth ground. Attempting to defeat the proper connection of the ground wire is dangerous for users and equipment.
   - Equipment maintenance, inspections, disinfection and cleaning should be as described in this manual.
3. Before powering on the system, the power cords and plugs should be inspected. Damaged electrical parts must be replaced immediately by authorized personnel.
4. Large gas cylinders provided by the manufacturer or purchased by the customer must be secured with cylinder safety chains or safety stands as required by local law.
5. After removing the protective cap of the cylinder you should inspect the cylinder valve for damaged threads, dirt, oil and/or grease. Any dust or dirt should be removed and the cylinder should not be used if oil or grease is present.
6. You should ensure that the pressure regulator is chemically and physically compatible with the intended gas cylinder before installation. The regulator must be properly connected. Note the pressure gauge for the regulator. The physical condition of the regulator, threads and fittings should also be examined prior to installation. Any dust or dirt on the regulator or cylinder valve should be removed with a clean cloth. The regulator should not be installed on a cylinder valve if grease or oil is present.
7. After connecting the regulator to the cylinder you should increase the regulator output pressure to the recommended value (5-6 bars/70-90 psi).
8. The cylinder and pressure regulator must be closed before disconnecting the cylinder from the device.
9. Residue and other contaminants in the breathing circuit pose a safety risk to the patient during testing procedures. Aspiration of contaminants can be potentially life-threatening. If the recommended disposable anti-bacterial filters are not used, you must disinfect each part coming into contact with the patient and patient's breath prior to each test.
10. The cleaning procedures and inspections in the System Maintenance section should be performed prior to each test.
11. This device should not be used in the presence of flammable anaesthetics. This is not an AP or APG device (according to the EN 60 601-1 definitions).
12. The device should not come near any heat or flame sources, flammable or inflammable liquids or gases and explosive properties.
13. The device should not be used in conjunction with any other medical device unless that device is recommended by the manufacturer.
14. The device should be used with a computer with electromagnetic compatibility, CE marking and low radiation emission displays.
15. The PC connected to the device must be compliant with EN 60601-1 by means of an isolation transformer.

16. Precautions regarding EMC should be taken prior to installation and can be noted in the section *EMC*.
17. Portable and mobile RF communication equipment may interfere with the performance of the device.
18. Only the cable and accessories supplied with the equipment should be used with the device. The use of accessories and/or cables other than those supplied may result in increased emissions or decreased immunity of the equipment.
19. The device should not be used adjacent to or stacked with other equipment. If this is necessary, you must verify that the device continues to operate normally in the configuration in which it will be used.
20. The graphical symbols used with the device are described below:


Applied part type B (EN60601-1)


Applied part type BF (EN60601-1)


OFF

ON


Protective earth ground


Alternating current


Potential equalization node


PC connection


Connector for the RH/TA sensor


TTL auxiliary input/output


USB connector


HR probe connector


Refer to the instructions for use

Contraindications

Performing forced expiratory manoeuvres involved in spirometry testing may be contraindicated in certain conditions.

Contraindications for the spirometry testing

Absolute contraindications

For FVC, VC and MVV tests:

- Post-operative thoracic surgery patients.

For FVC tests:

- Severe instability of the airways (patients with severe Emphysema).
- Bronchial non-specific marked hypersensitivity.
- Severe gas exchange impairment (total or partial respiratory insufficiency).

Relative contraindications

For FVC tests:

- Spontaneous post-pneumothorax.
- Arterial-venous aneurysm.
- Severe arterial hypertension.
- Pregnant with complications in the 3rd month.

For MVV tests:

- Hyperventilation syndrome.

Contraindications for Bronchial Provocation testing

Bronchial Provocation testing must be executed under the direction of a physician. Testing is considered safe when executed properly in a clinical setting, but the following contraindications should be acknowledged prior to testing:

Absolute contraindications

- Severe bronchial obstruction (decreased FEV_1 in adults).
- Recent myocardium infarct.
- Recent cerebral vascular accident.
- Known arterial aneurysm.
- Incapacity for understanding the provocation test procedures and its implications.

Relative contraindications

- Bronchial obstruction caused by performing respiratory manoeuvres.
- Moderate or serious bronchial obstruction (FEV_1 < 1.51 in men and FEV_1 < 1.21 in women).
- Recent respiratory infection.
- Recent Asthma exacerbation.
- Hypertension
- Pregnancy
- Epilepsy

Contraindications for Exercise testing

Absolute contraindications

- Acute MI (within 2 days)
- High-risk unstable angina
- Uncontrolled cardiac arrhythmias causing symptoms of hemodynamic compromise
- Active endocarditis
- Symptomatic severe aortic stenosis
- Decompensated symptomatic heart failure
- Acute pulmonary embolus or pulmonary infarction
- Acute noncardiac disorder that may affect exercise performance or be aggravated by exercise (eg, infection, renal failure, thyrotoxicosis)
- Acute myocarditis or pericarditis
- Physical disability that would preclude safe and adequate test performance
- Inability to obtain consent

Relative contraindications

- Left main coronary stenosis or its equivalent
- Moderate stenotic valvular heart disease
- Electrolyte abnormalities
- Tachyarrhythmias or bradyarrhythmias
- Atrial fibrillation with uncontrolled ventricular rate
- Hypertrophic cardiomyopathy
- Mental impairment leading to inability to cooperate
- High-degree AV block

> ***Note:*** *Relative contraindications can be superseded if benefits outweigh risks of exercise.*

Read carefully the exercise testing chapter.

Environmental condition of use

COSMED units should not be operated near explosive substances.

Equipment should not be installed near electrical or magnetic devices such as x-ray equipment, transformers or power lines. These devices could create electrical interferences when performing testing procedures. COSMED devices are not AP or APG units (according to EN 60601-1) and should never be operated in the presence of flammable anaesthetic mixtures.

COSMED equipment should be operated under normal environmental temperatures and conditions which are defined as follows [IEC 60601-1/EN 60601-1]:

- Temperatures range: 10°C (50°F) and 40°C (104°F).
- Relative humidity range: 30% to 90% (not condensing).
- Atmospheric Pressure range: 600 mBar to 1060 mBar.
- Avoid operating equipment in the presence of noxious fumes or in dusty environments.
- Do not place units near heat sources.
- Cardiopulmonary resuscitation equipment should be accessible in the case of an emergency.
- Adequate floor space and easy access to the patient during exercise testing is necessary.
- Adequate ventilation should be maintained in the room the testing is performed.

EMC

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emission IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emission IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**Test level IEC 60601-1**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Nota: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**Test level IEC 60601-1**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance** $d=1.17\sqrt{P}$ $d=1.17\sqrt{P}$ 80 MHz to 800 MHz $d=2.33\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Notes: (1) At 80 MHz, the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m			

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz d=1.17 $\sqrt{P}$	**80 MHz to 800 MHz** d=1.17 $\sqrt{P}$	**800 MHz to 2.5 GHz** d=2.33 $\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.38
100	11.70	11.70	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

(1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Overview of the manual

This manual is organized in the following chapters:

Getting started. Describes the intended use of the device, how to properly use it and features of the unit and accessories.

Installation. Lists the steps required to properly install the device.

System maintenance. Describes system maintenance procedures.

Appendix. Contains information regarding the warranty, treatment of personal data, reference standards, technical features, predicted values and bibliographic references.

Software and test execution are described in the Software Manual. We recommend to read both manuals before using this device.

Introduction

The Quark is the designed for evaluation of the cardiorespiratory system.

The system can perform spirometry, lung volumes, diffusion or exercise testing.

The Quark can be configured with the following modules according to the user's needs:

	Quark Spiro	Quark PFT	Quark CPET
Spirometry	☑	☑	○
Lung volumes	-	○	-
DLCO	-	○	-
Respiratory mechanics	-	○	-
CPET	-	○	☑
Dosimeter	○	○	-
Oximeter	○	○	○
Airway resistances	○	○	-
Nutritional (Canopy)	-	○	○
Mixing Chamber	-	○	○
Quark C12	-	○	○

☑ In the packaging

○ Optional

The Quark Spiro and Quark PFT should be configured with either the turbine flowmeter or PNT.

Each module will allow the following tests to be performed:

Spirometry: FVC, VC, and MVV.

Lung volumes: FRC (via Nitrogen Wash-out) and Closing Volume.

DLCO: Diffusion capacity (with or without apnoea or intra-breath method).

Respiratory mechanics: MIP/MEP and P0.1.

CPET: Breath by breath exercise testing.

Dosimeter: Allows measurements to be obtained after the delivery of broncho-provocators according to standardized protocols.

Oximeter: Oximetry tests.

Airway Resistance: Airway Resistance via the interruption method.

Nutritional (Canopy): Resting Metabolic Rate.

Mixing Chamber: Exercise testing using the mixing chamber technique (ideal for sports medicine).

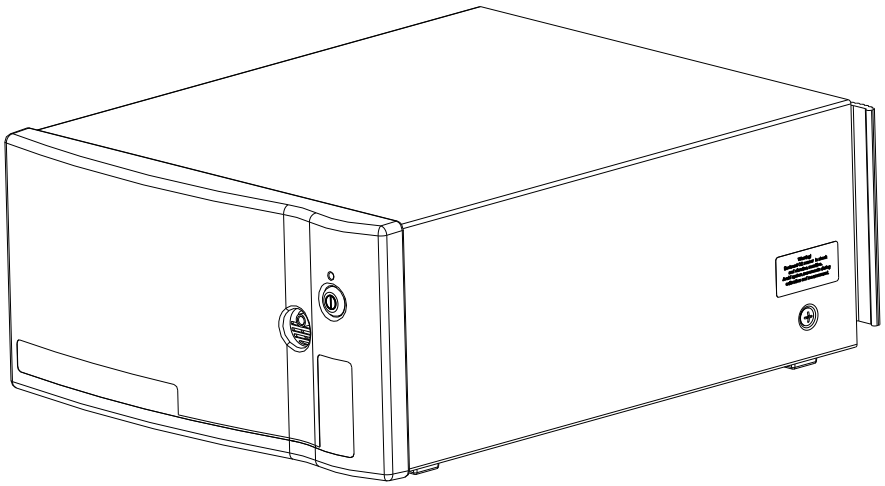
Quark C12: Incorporates the ECG during exercise testing.

System overview

The Quark consists of the following parts:

- Quark unit
- Flowmeter
- Breathing valve
- Additional external sensors and devices (temperature-humidity, HR, oximeter).

Quark unit



The Quark unit contains the following elements:

- The power switch (located on the front panel)
- Connectors (located on the rear panel)

Powering on the device

When the unit is plugged in, press the power switch on the front panel. The green led above the switch will turn on, indicating that the Quark is on.

Powering off the device

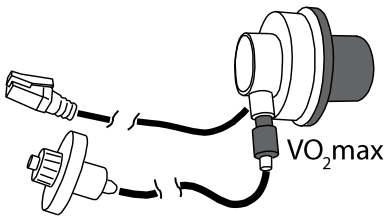
Press the power switch on the front panel. The green led above the switch will turn off, indicating that the Quark is no longer running.

The flowmeter

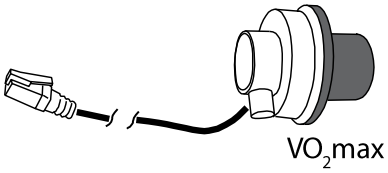
Turbine flowmeter

The turbine flowmeter assembly consists of a bidirectional turbine and an optoelectronic reader. The reader measures infrared light interruptions caused by the spinning blade inside the turbine. The device may be used to measure a wide flow range and is not affected by ambient conditions (pressure, humidity, room temperature, exhaled gas composition). Daily calibration of the turbine is not necessary, but calibrations should be performed regularly to assure accurate measurements.

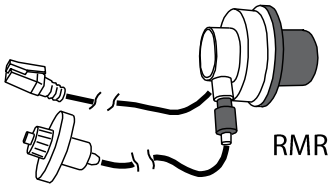
There are three turbine flowmeters: ID28, ID28 Spiro and ID18.



The ID28 flowmeter can be used for all tests except for RMR testing and is provided with the Quark PFT and Quark CPET modules.

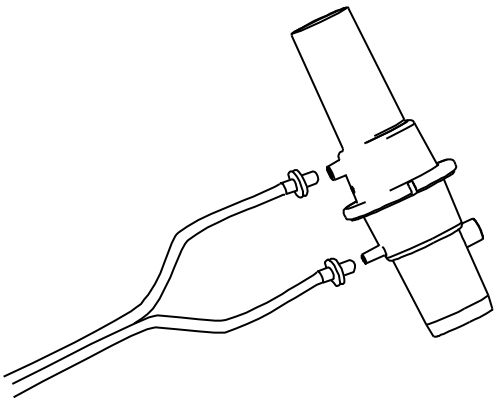


The ID28 flowmeter is identical to the ID28 with the absence of a sampling line. This flowmeter should only be used for spirometry testing when exhaled flow gas analysis is not necessary. This flowmeter is provided with the Quark Spiro module.



The ID18 flowmeter is used for RMR testing and it is provided with the Nutritional modules.

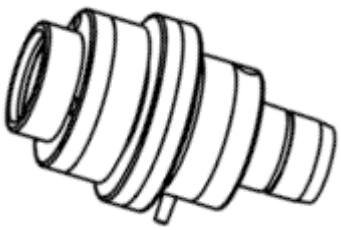
Pneumotach Flowsafe



The PNT flow measurements are obtained by measuring the pressure differential between the two sides of a polyester net. The device may be used to measure a wide flow range and is not affected by ambient conditions (pressure, humidity, room temperature, exhaled gas composition). Daily calibration of the PNT is not necessary, but calibrations should be performed regularly to assure accurate measurements.

The PNT should be used for spirometry testing only.

Pneumotach X9



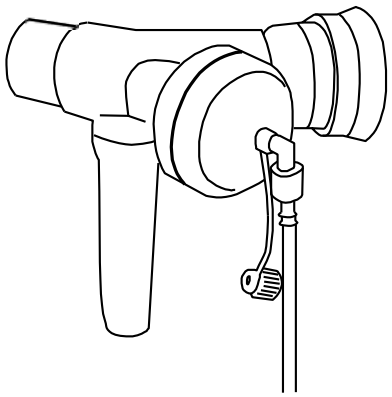
As for the Flowsafe, the X9 calculates the flow by measuring the differential pressure between the two sides of a polyester net.

Differently from the Flowsafe, the X9 can be reused, after proper disinfection, must be calibrated as the turbine flowmeter and can be used for all spirometry tests.

Each X9 is shipped with customized linearization tables. It is necessary to load the tables from the included USB key into the software, see section *Calibration*. The USB key and X9 will have the same serial number.

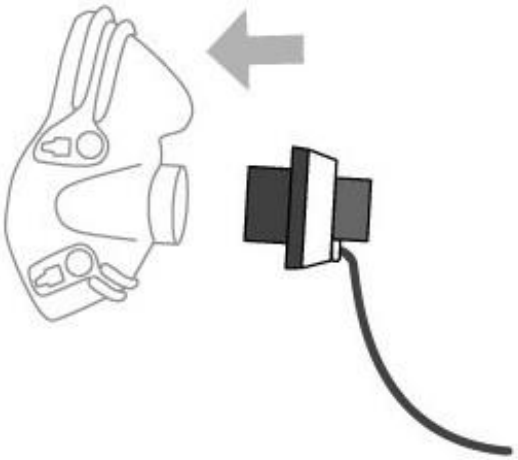
> ***Note:*** *The PNT X9 must be used with the COSMED antibacterial filter.*

The breathing valve



This breathing valve allows the breathing circuit to automatically switch between the demand valve (connected to the gas cylinder) and ambient air. This valve closes during DLCO testing to block the air going to the patient during the required apnea time. The body of the valve is made of ABS plastic with a silicone membrane used to open and close the breathing circuit. The valve is easily connected to the flowmeter and easily disassembled for disinfection. Either the patient should hold the valve or an articulated arm should can be used to support it.

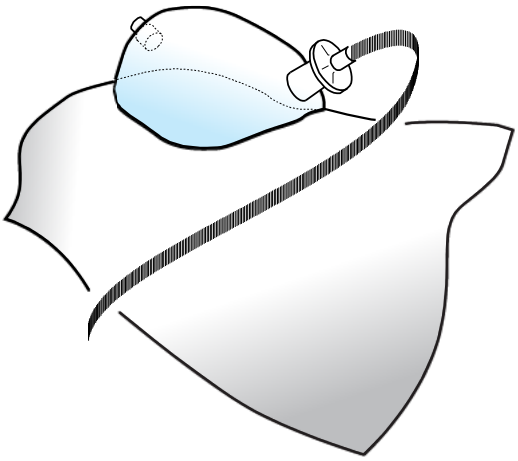
The exercise test mask



The exercise test masks are made of silicone and may be reused after proper disinfection (see the chapter *Maintenance*).

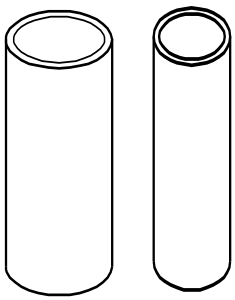
These blue masks are available in different sizes and should be assembled the included head cap as shown in the chapter *Exercise testing*.

The canopy hood



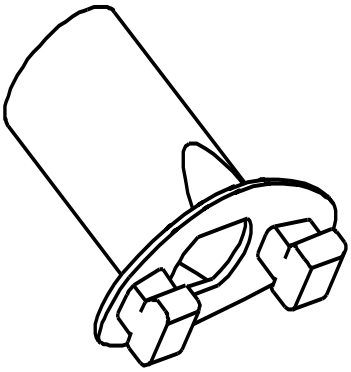
The canopy hood allows the patient's exhaled air to blend with ambient air. This mixture is then inspired by a pump with a known flow and the patient's Oxygen Consumption, CO_2 production and Energy Expenditure can be calculated.

Paper mouthpieces



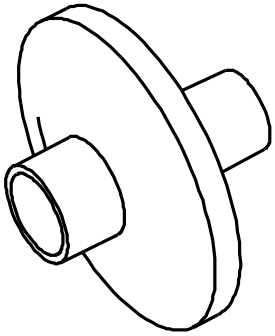
Paper mouthpieces are available for basic spirometry tests (FVC, VC, and MVV). The mouthpieces should not be used for any other testing.

PTE soft mouthpieces



The PTE soft mouthpieces are available for all tests other than spirometry.

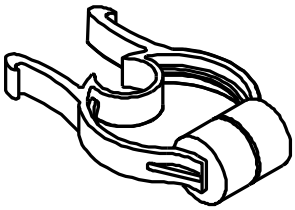
Antibacterial filters



The use of antibacterial filters is recommended for infection control. However, regular cleaning and decontamination of lung function equipment should always be performed.

> ***Note:*** *The use of antibacterial filters is recommended even when using disposable mouthpieces to prevent cross-contamination.*

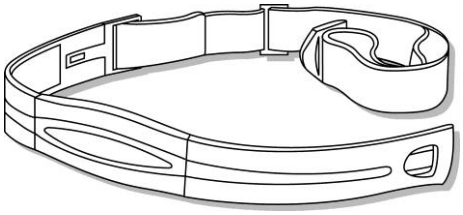
Nose clips



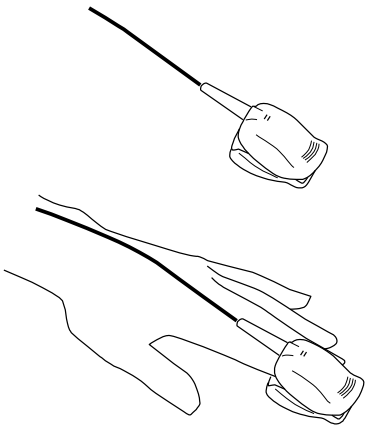
Nose clips should be used during spirometry testing to prevent respiration through the nasal passage while performing testing manoeuvres.

The HR probe

The HR probe consists of three parts: the elastic belt containing the transmitter and the USB receiver. The parts should be assembled as close as possible to one another to acquire the most effective communication signal.

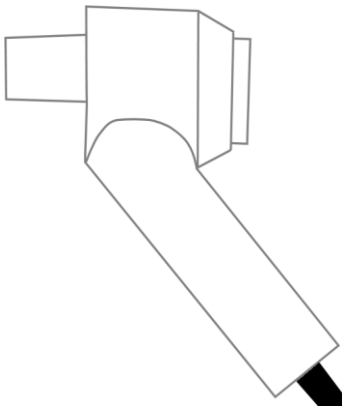


The oximeter



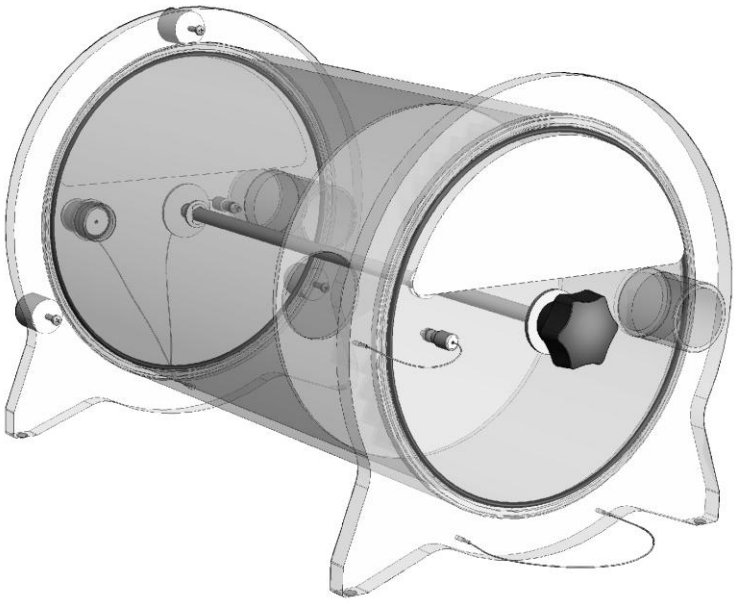
The oximeter probe should be placed on the patient's finger to measure oxygen saturation at rest or during exercise.

The R_{OCC} PNT



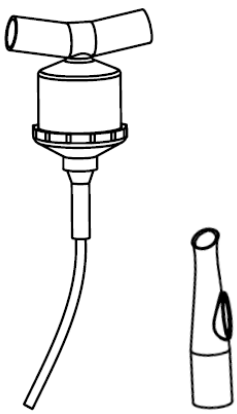
The R_{occ} PNT allows the measurement of airway resistance by implementing the interruption technique.

The mixing chamber



The mixing chamber is a 8.7-litres plexiglas box, for exercise or resting tests with the classic mixing chamber technique instead of the breath by breath one.

The dosimeter



The dosimeter is made of a nebulizer and accessories for the bronchoprovocator to be given to the patient, for bronchoprovocation tests.

Its packaging includes the nebulizer, a tubing for the Quark connection, a mouthpiece and different adapters. Its use is described in the chapter *The dosimeter*.

System warm-up

Before using the Quark the system must be warmed up for the required amount of time. The warm-up time duration depends on which test is being performed. The following table displays the warm-up time required for each test:

Test	Warm-up time (mins)
FVC, VC, MVV	-
FRC	5
CV	5
DLCO	15
MIP/MEP	-
P0.1	-
Oximetry	-
R_{OCC}	-
CPET	5
RMR	5

During the warm-up period the device must be powered on, but the software does not need to be open.

Calibration and/or testing procedures should never be performed until the warm-up period has been completed.

Installation

Before starting

Before operating the Quark you should inspect the equipment and complete the product registration.

Checking the packing contents

When opening your product you should assure that the package contains all items listed below. If there are any missing or damaged parts you should contact Cosmed's technical assistance.

> ***Note:*** *Actual packaging of device and modules could differ from the one specified below depending on the actual device's configuration.*

Device packaging

Quark Spiro standard packaging

Code	Quantity	Description
C00971-01-04	1	Quark Spiro Unit
A-662-100-001	2	Nose clips
C02656-01-06	1	T/RH probe
A-362-050-001	1	Power cable
A-362-300-001	1	RS232 cable
A-362-315-001	1	USB cable
A-680-024-125	2	Time lag fuse 5x20 250V T1,25A
C01788-01-36	1	PC software PFT
C03262-02-91	1	User Manual
C03939-02-91	1	Software manual

Quark PFT standard packaging

Code	Quantity	Description
C00972-02-04	1	Quark PFT Unit
C02290-01-05	1	Smart valve with hoses
A-662-100-001	2	Nose clips
C02656-01-06	1	T/RH probe
C00600-01-11	1	3 litres calibration syringe
A-362-050-001	1	Power cable
A-362-300-001	1	RS232 cable
A-362-315-001	1	USB cable
A-680-024-125	2	Time lag fuse 5x20 250V T1,25A
C01788-01-36	1	PC software PFT
C03047-01-20	1	RMR Flowmeter syringe adapter
C03110-01-10	1	VO2 Max Flowmeter syringe adapter
C03262-02-91	1	User Manual
C03939-02-91	1	Software manual

Quark CPET standard packaging

Code	Quantity	Description

C00973-02-04	1	Quark CPET Unit
C03400-01-04	2	ID28 turbine
C02500-02-04	1	ID18 turbine
C03095-01-08	1	Handle for optoelectronic reader
A-662-100-001	2	Nose clips
C02656-01-06	1	T/RH probe
C03611-01-10	1	Mask VO_2max Small
C03612-01-10	1	Mask VO_2max Medium
C03613-01-10	1	Mask VO_2max Large
A-800-900-022	1	Head cap for the adult masks (L)
A-800-900-023	1	Head cap for the adult masks (S, M)
C00136-01-20	50	Adult paper mouthpieces
C00137-01-20	50	Paediatric paper mouthpieces
A-182-300-004	5	Antibacterial filters
C02210-02-08	1	Permapure sample line 2m
C03232-01-10	1	Ergo hose
C00214-01-20	1	OD22 paediatric adapter
A-661-200-071	1	Elastic belt
A-661-200-070	1	HR monitor
A-661-200-039	1	HR receiver
A-362-315-010	1	USB extension cable
C00600-01-11	1	3 litres calibration syringe
A-362-050-001	1	Power cable
A-362-300-001	1	RS232 cable
A-362-315-001	1	USB cable
A-680-024-125	2	Time lag fuse 5x20 250V T1,25A
C03047-01-20	1	RMR Flowmeter syringe adapter
C03110-01-10	1	VO2 Max Flowmeter syringe adapter
C01790-01-36	1	PC software CPET
C01788-01-36	1	PC software PFT
C03262-02-91	1	User Manual
C03939-02-91	1	Software manual

Packaging of optional products

Turbine (ID28) Option standard packaging

Code	Quantity	Description
C03400-01-04	2	ID28 turbine
C03095-01-08	1	Handle for optoelectronic reader
C00136-01-20	50	Adult paper mouthpieces
C00137-01-20	50	Paediatric paper mouthpieces
A-182-300-004	5	Antibacterial filters
C02210-02-08	1	Permapure sample line 2m
C00214-01-20	1	OD22 paediatric adapter

PNT Option standard packaging

Code	Quantity	Description
C03600-01-05	2	PNT X9
C03095-01-08	1	Handle for reader
A-182-300-004	5	Antibacterial filter
C02210-02-08	1	Permapure 2m

Spiro Turbine (ID28) Option standard packaging

Code	Quantity	Description
C02550-01-04	2	ID28 turbine
C03095-01-08	1	Handle for optoelectronic reader
C00136-01-20	50	Adult paper mouthpieces
C00137-01-20	50	Paediatric paper mouthpieces
A-182-300-004	5	Antibacterial filters
C00214-01-20	1	OD22 paediatric adapter

Lung Volumes module standard packaging

Code	Quantity	Description
C02380-01-06	1	Smart valve
C00269-01-20	5	PTE ID25mm soft mouthpiece
A-182-300-004	5	Antibacterial filters
C03563-01-10	1	FRC hose
C03564-01-10	1	Ergo hose
C02226-01-20	1	Membrane for Smart Valve

DLCO module standard packaging

Code	Quantity	Description
C02380-01-06	1	Smart valve
C00269-01-20	5	PTE ID25mm soft mouthpieces
A-182-300-004	5	Antibacterial filters
C03562-01-10	1	DLCO hose
C02226-01-20	1	Membrane for Smart Valve

Respiratory Mechanics Module standard packaging

Code	Quantity	Description
C03268-01-08	1	Pressure line respiratory mechanics
C00269-01-20	5	PTE ID25mm soft mouthpieces

CPET Module standard packaging

Code	Quantity	Description
C03400-01-04	1	ID28 turbine
C03611-01-10	1	Mask VO_2max Small
C03612-01-10	1	Mask VO_2max Medium
C03613-01-10	1	Mask VO_2max Large
A-800-900-022	1	Head cap for the adult masks (L)
A-800-900-023	1	Head cap for the adult masks (S, M)
C02210-02-08	1	Permapure sample line 2m

C03564-01-10	1	Ergo hose
C02500-02-04	1	ID18 turbine
A-661-200-071	1	Elastic belt
A-661-200-070	1	HR monitor
A-661-200-039	1	HR receiver
A-362-315-010	1	USB extension cable
C03309-01-12	1	PFT input/output HR TTL cable
C01790-01-36	1	PC software CPET

Oximeter module standard packaging

Code	Quantity	Description
A-661-600-007	1	Oximeter

Airway Resistances module standard packaging

Code	Quantity	Description
C02410-02-04	1	R_{OCC} Unit
C02420-01-08	1	PNT R_{OCC}
A-182-300-004	5	Antibacterial filters
C00311-01-20	1	Silicone hose
A-662-100-001	2	Nose clips

Nutritional module standard packaging

Code	Quantity	Description
C02500-01-04	1	ID18 turbine
C03880-01-10	1	Quark RMR bubblehood
C02678-01-07	1	Canopy wrinkled tube
C03886-01-10	1	Canopy vail
C00965-01-04	1	Canopy unit
A-182-300-004	5	Antibacterial filter
C03729-01-30	1	Canopy power supply
A-182-300-004	10	Antibacterial filter
C00269-01-20	5	Soft mouthpiece (PTE ID25mm)
A-662-100-001	2	Nose clip
C01788-01-36	1	PC Software PFT
C01790-01-36	1	PC software CPET

Mixing chamber module standard packaging

Code	Quantity	Description
C03348-01-04	1	Mixing chamber
C03189-01-05	1	Two-way non rebreathing valve
A-800-900-025	1	Head support for 2-ways valve
C02106-01-08	1	Head cap Large
A-108-300-008	1	Wrinkled tube
C02106-01-08	1	Spirometry mouthpiece adapter
C02181-01-08	1	Adapter for reader
C03427-01-94	1	Start up guide
C02753-01-10	1	Mixing chamber mask Medium

C01788-01-36	1	PC Software PFT
C01790-01-36	1	PC software CPET

Dosimeter module standard packaging

Code	Quantity	Description
C03560-01-11	1	Dosimeter kit
C03515-01-08	1	Dosimeter tube
C03482-01-08	1	Nebulizers holder
C03222-01-20	2	Dosimeter adapter
C03425-01-20	2	Flowsafe-antibacterial filter adapter
A-862-010-001	6	DeVilbiss 646 Nebulizer
A-661-919-003	10	Mouthpieces
A-182-300-004	10	Antibacterial filter

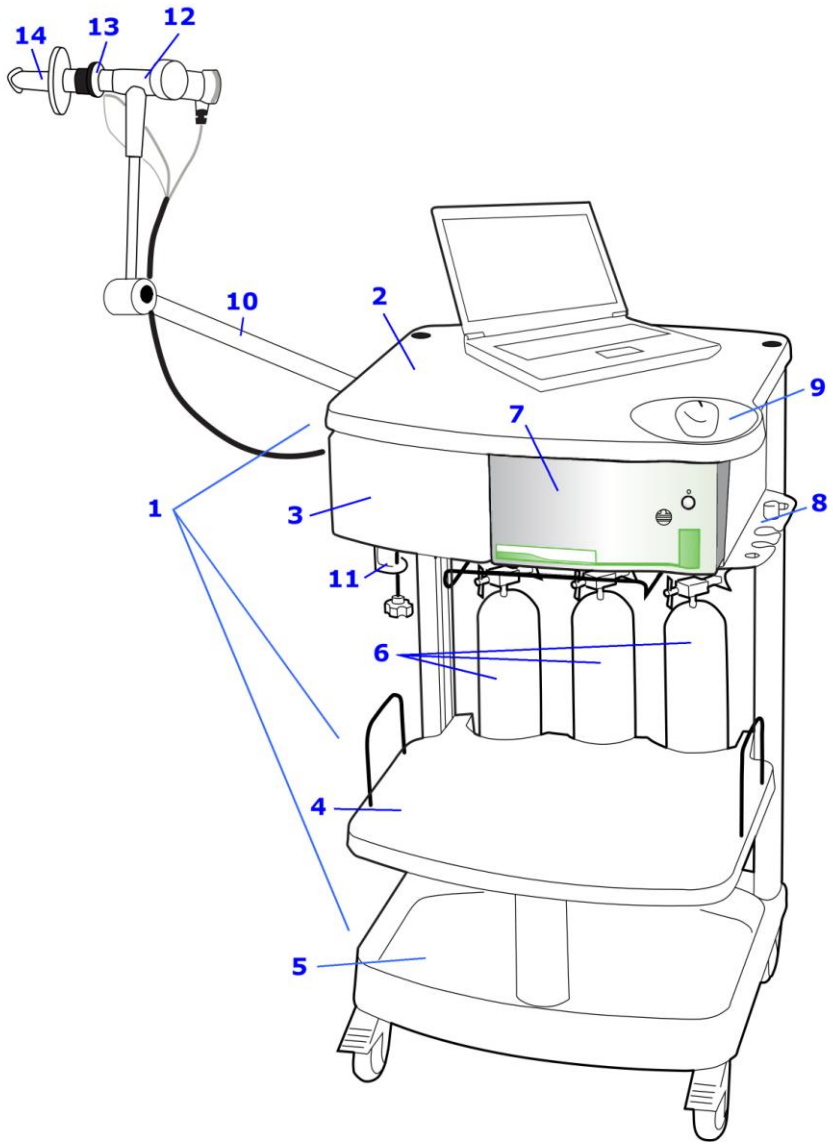
Options/Accessories

The following options are available with the Quark system:

Code	Quantity	Description
A 860 000 004	1	Calibration cylinder (5% CO_2, 16% O_2, balance N_2)
A 860 000 005	1	DLCO cylinder (0.3% CO, 0.3% CH_4, 21% O_2, bal. N_2)
A 860 000 006	1	DLCO cyl. st. state (0.1% CO, 0.1% CH_4, 21% O_2, bal.N_2)
A 860 000 007	1	Oxygen cylinder
C02900-01-04	1	Trolley (without arm)
C02870-01-04	1	Arm for trolley
A 870 150 005	1	Pressure regulator for cal./DLCO cylinder
A 870 150 006	1	Pressure regulator for O_2 cylinder
C03101-01-10	1	Paediatric mask Small for RMR
C03102-01-10	1	Paediatric mask Large for RMR
C03103-01-10	1	Paediatric mask Large for VO_2max

System description

The Quark system consists of the main unit and its accessories. The following picture displays the correct assembly.



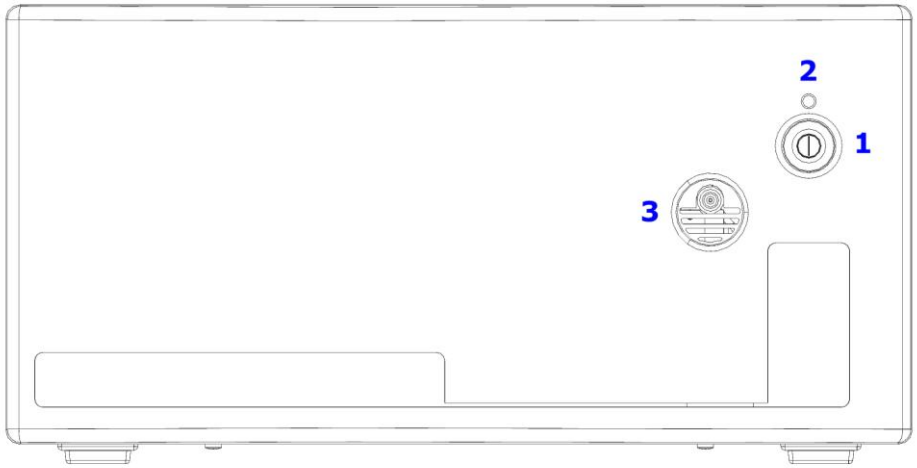
1. Trolley
2. PC shelf
3. Drawer
4. Printer shelf
5. Supplementary shelf
6. Cylinders
7. Quark unit
8. Location for smart valve, turbine, etc.
9. Mouse shelf
10. Arm
11. Vice for arm fixing
12. Breathing valve
13. Turbine

14. Antibacterial filter

Quark installation

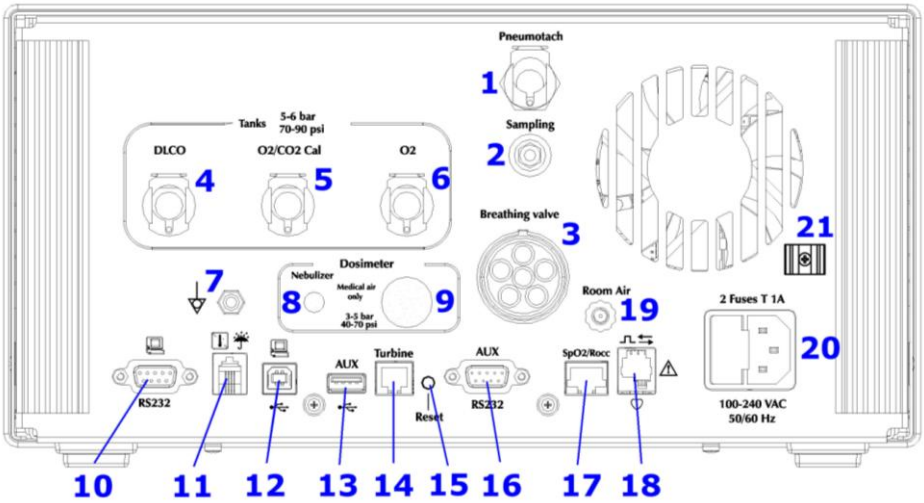
Before operating the system you should make sure that environmental and operational conditions have been met (see Chapter 1).

Quark front panel



1. Power switch
2. Led on/off
3. Gas calibration connection

Quark rear panel



1. PNT/MIP-MEP/P0.1 connector
2. Permapure sampling line connector
3. Breathing valve connector
4. DLCO cylinder connector
5. O_2/CO_2 cylinder connector
6. Oxygen cylinder connector
7. Supplemental earthing terminal
8. Dosimeter connector
9. Medical air connector

10. RS232 connector for PC
11. Temp/RH probe connector
12. USB connector for PC
13. Auxiliary USB connector (for HR probe)
14. Turbine connector
15. Reset button
16. Auxiliary RS232 connector (for ergometer control)
17. Oximeter/PNT R_{OCC} connector (for PNT $R_{OCC,}$ an adapter is required)
18. Auxiliary TTL input/output
19. Connector for the soda lime CO_2 absorber output (already connected)
20. Power cable plug
21. Soda lime CO_2 absorber slot (already connected)

Calibration cylinders

In order to calibrate the sensors, the following calibration cylinders are required:

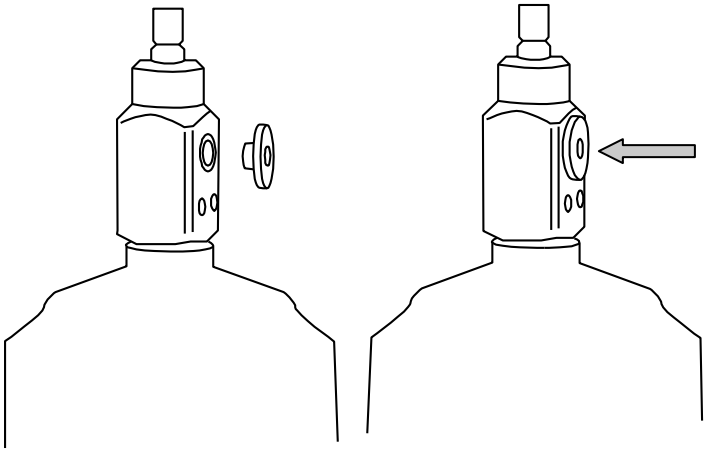
Cylinder	Recommended Gas Mixture	Test
Calibration	O_2 16%, CO_2 5%, N_2 Bal	FRC, CV, CPET, RMR
DLCO	CO 0.3%, CH_4 0.3%, O_2 21%, N_2 Bal	DLCO
Oxygen	O_2 100 %	FRC, CV

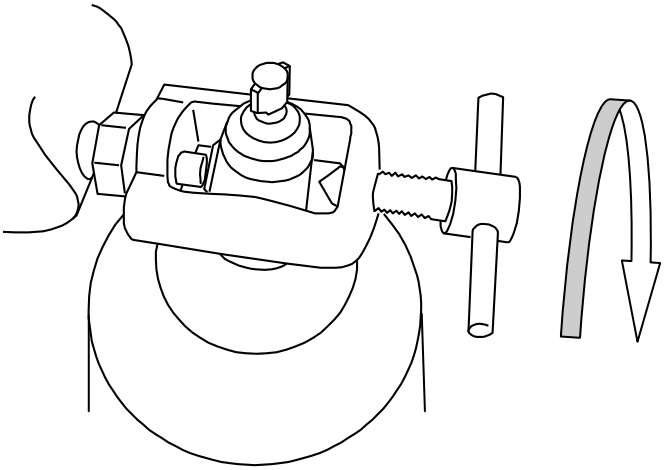
Cylinder can be placed into the trolley housings (option).

> ***Note:*** *The cylinders must contain a calibration certificate which indicates the gas concentrations.*

Assembling the gas regulators on the cylinder

Attach the gas regulator on the cylinder as shown in the following picture. The white washer should be inserted between the cylinder and the gas regulator.



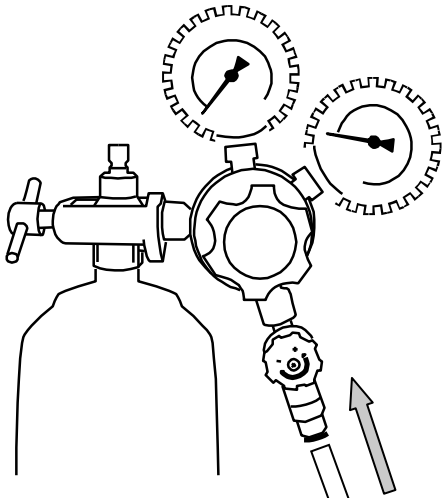


Warning: *The regulator should be tightly connected to avoid leaks.*

Note: *Gas regulators have different adapters depending on the gas mixture they are created for. Assure that the proper gas regulator has been chosen for the cylinder in use.*

The gas regulator has an adjustable second stage that must be adjusted when used for the first time. This is necessary to protect the internal demand valve from the high pressure generated when the cylinder is opened.

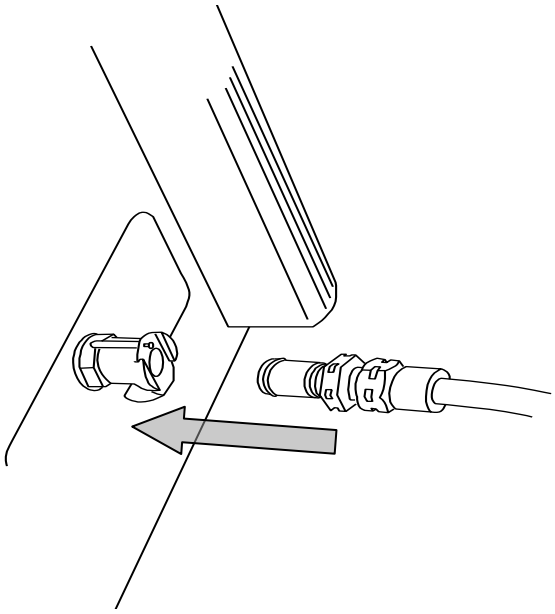
Connecting the hoses to the cylinders



Note the following table in order to find the appropriate coloured hose for the cylinder in use (the colour represents the different connectors used at the end of the hose):

Cylinder	Connector colour
Calibration	Blue
DLCO	Green
Oxygen	White

Connecting the cylinders to the Quark



> ***Warning:*** *The pressure knobs must be closed before connecting the cylinders to the Quark (turn counter clockwise).*

1. Connect the cylinders to the Quark, making sure to match the appropriate coloured connectors.
2. Assure that the pressure adjustment knob is closed (by turning it counter clockwise).
3. Open the cylinder by turning the valve on the top of the cylinder counter clockwise and the tap under the gas regulator counter clockwise.

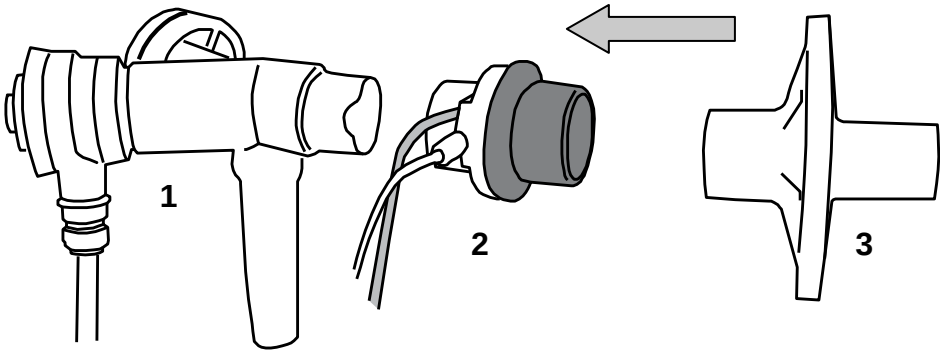
> ***Note:*** *To ensure a long cylinder life, you should not force the valve to its maximum opening and you should avoid opening and closing the valve repeatedly. To close the cylinder for a short period of time you may simply close the black tap under the gas regulator.*

4. Turn the pressure adjustment knob clockwise and adjust the pressure between 5 and 6 bars (70-90 psi).

Cylinders should be replaced when the internal pressure falls below 10 bars (150 psi).

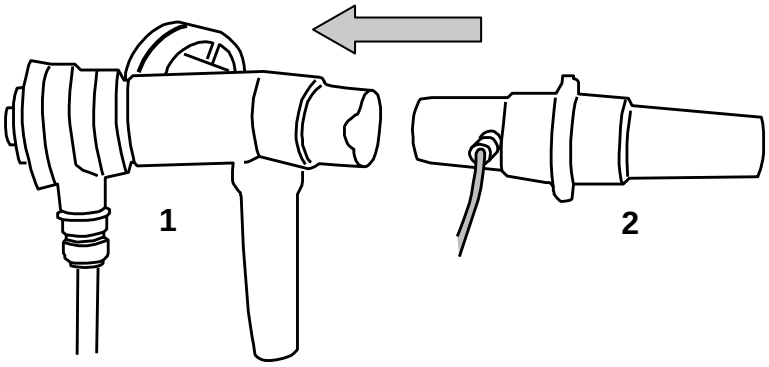
> ***Caution:*** *You should always close the cylinder and the gas regulator before disconnecting the hoses from the Quark.*

Assembling the breathing valve and the flowmeter



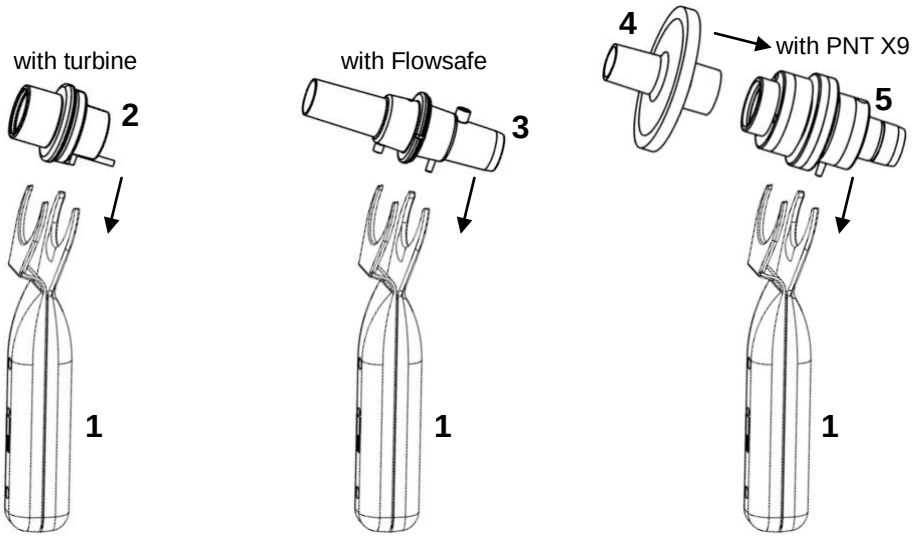
1. Breathing valve
2. Turbine
3. Antibacterial filter

Align the sampling line onto the turbine with the tooth on the smart valve.



1. Breathing valve
2. PNT

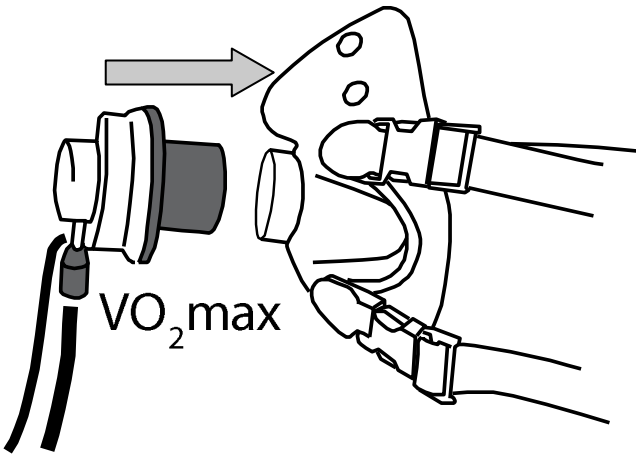
Assembling the flowmeter to the handle



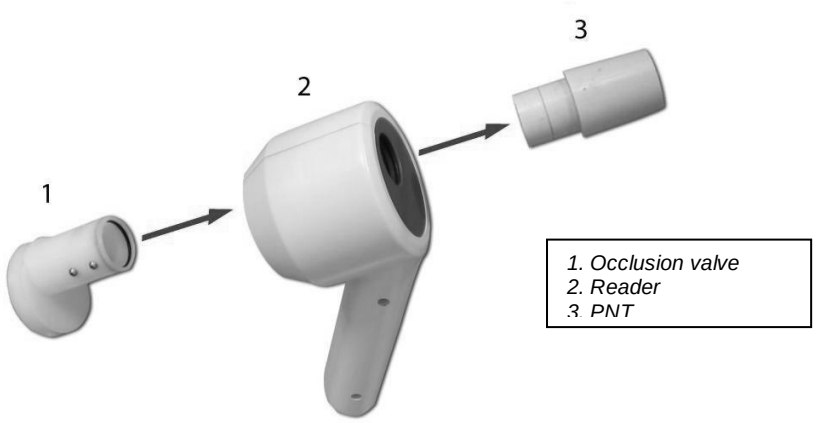
1. Handle
2. Turbine ID28
3. Flowsafe
4. Antibacterial filter
5. PNT X9

Note: *in order to obtain reliable measurements, the PNT X9 must be always used with the antibacterial filter.*

Assembling the VO_2max mask and the flowmeter



Assemble the R_{OCC} PNT



1. Occlusion valve
2. Reader
3. PNT

Connecting the Quark to the PC

Connect the Quark unit to the PC through the RS232 or USB port by connecting the cable (RS232 or USB) to the proper (COM or USB) Quark and PC ports.

Connecting the Quark to the power supply through the trolley

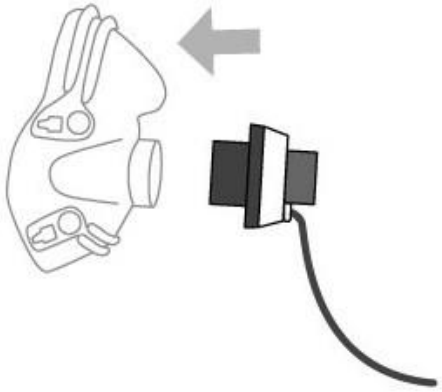
1. Connect the Quark unit to the trolley through the power cable.
2. Connect the PC, monitor and printer to the trolley through their power supply cables.
3. Connect the trolley to the wall through its power cable. The trolley has a separate switch on the back of the cart.

> ***Warning:*** *Always turn off the trolley and the Quark when not in use.*

Preparing the device and the patient for exercise testing

Preparing the Quark

Connect the head cap, the VO_2max mask and the ID28 turbine as shown in the following picture:



The head cap and mask can be connected by the white clips.

The turbine and HR probe should be connected to the rear panel of the Quark.

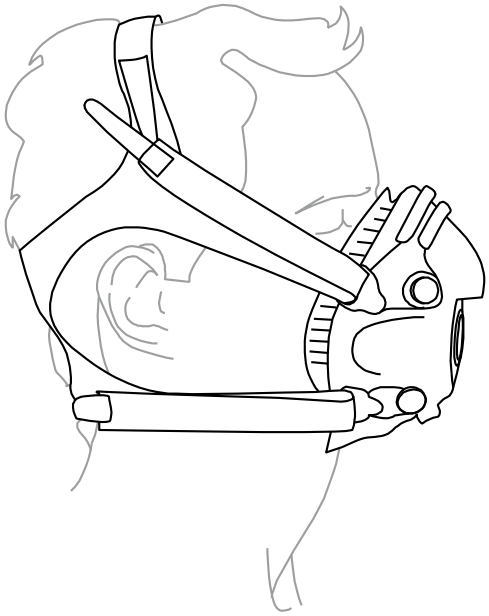
If you choose to drive an ergometer with the Quark, connect the ergometer cable to the RS232 port on the rear panel of the Quark with the serial port provided in the packaging. Select the ergometer to be used before starting the test.

> ***Note:*** *Cellular phones should be turned off to eliminate potential electrical interferences.*

Patient preparation

The mask

Fix the mask as illustrated in the picture below. Adjust the elastic bands on the head cap as necessary to eliminate possible leaks and create a tight seal around the subject's face.

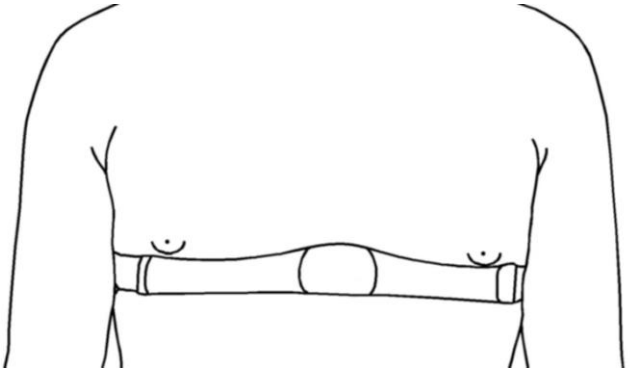


The HR elastic belt

To assemble the HR belt:

1. Attach the Transmitter to the elastic strap.

2. Adjust the strap to fit tightly and comfortably around the subject's thorax.
3. Secure the strap tightly around the chest (below the nipple line) and lock the buckle.



4. You may wet the grooved electrode areas with saliva, contact lens solution or an alternative saline solution to help it stick to the subject.

The transmitter should be worn against bare skin to ensure successful operation. If a transmitter is worn over a shirt, the shirt should be wet underneath the electrode area to achieve proper conductivity.

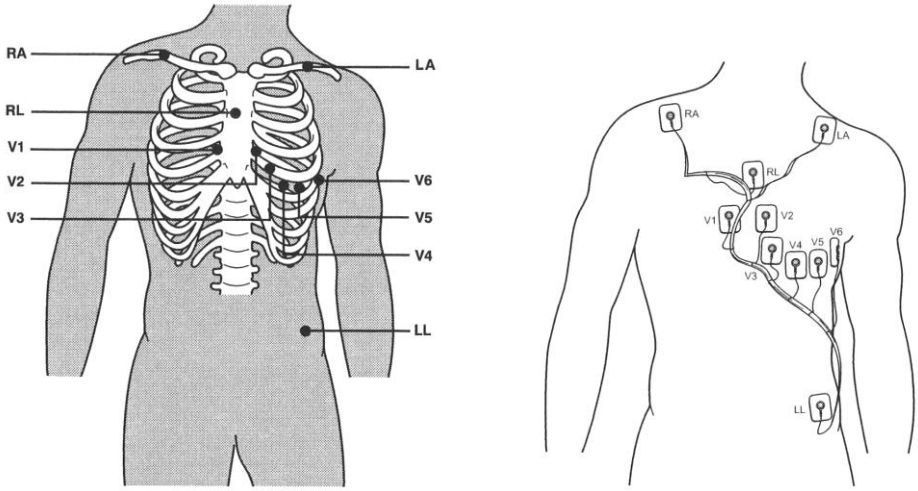
To acquire the most accurate HR signal you should place the HR probe as close as possible to the HR belt.

ECG electrodes

Correct electrode placement is important for acquiring a successful ECG signal. Patient preparations that may be performed to improve the signal include the removal of oils, lotions and hair from the skin.

1. Shave the area in which the electrodes will be placed.
2. Using a slightly abrasive cloth, cut an X where the electrodes will be placed.
3. Rub the area with gauze that has been saturated with either ether or acetone.
4. Remove any residual with dry gauze.
5. Apply the patient cable to the electrodes and place them as shown in the following picture.

> ***Note:*** *The patient cable and the transmitter are not water-proof. You should prevent any liquids from penetrating the area and avoid submerging the electrodes in liquid.*



The electrodes should be placed as follows:

V1 4th intercostal space, to the right of the sternum.

V2 4th intercostal space, to the left of the sternum.

V3 Between V2 and V4 electrodes.

V4 5th intercostal space, on the midclavicular line.

V5 5th intercostal space, on the anterior axillary line.

V6 5th intercostal space, on the left midaxillary line.

Limb electrodes for the arms should be placed in the subclavicular areas.

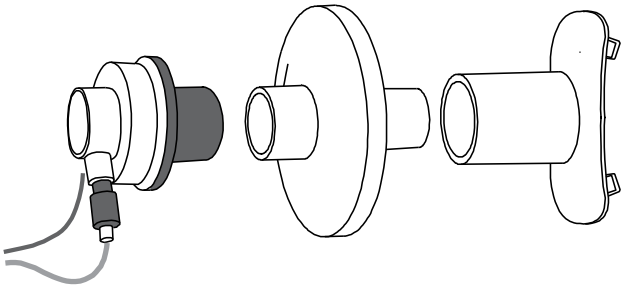
Limb electrodes for the legs should be placed on the trunk at the level of the bottom rib.

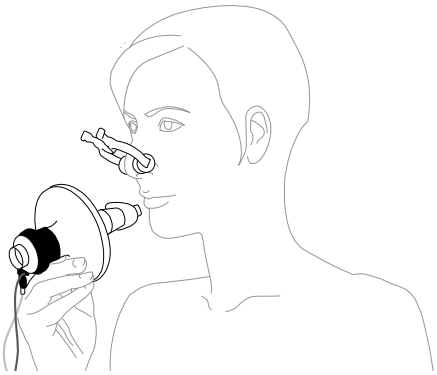
Warning: *QRS morphology may be slightly different from the standard ECG due to the different positioning of lower limb electrodes. To reduce these differences attempt to position the LL electrode as low as possible.*

Using a mouthpiece instead of a face mask

When performing sub-maximal tests (with ventilation values maintained at less than 100 L/min) you may use the combination rubber mouthpiece, filter and nose clip in place of the mask.

Assemble the mouthpiece, filter and reader as illustrated in the following picture. Assure that no leaks are present between the patient and the mouthpiece.





How to contact COSMED

You may contact the manufacturer directly at the following address for information:

COSMED S.r.l.
Via dei Piani di Monte Savello, 37
00041 - Pavona di Albano
Rome - ITALY

Voice: +39 (06) 931.5492
Fax: +39 (06) 931.4580
email: **customersupport@cosmed.it**
Internet: **http: //www.cosmed.com**

Complaints, feedback and suggestions

If you have any complaints, feedback or suggestions you may inform us at **complain@cosmed.it.**

System maintenance

System maintenance

Any service operations not specified in this user manual should be only performed by qualified personnel in accordance with the service handbook.

Rubber mouthpieces, face masks, breathing valves and the other parts are not shipped sterile. These should be disinfected before using according to the instructions in this section.

All materials used in the construction of the Quark and its accessories are non toxic and pose no safety risks to the patient or operator.

The device should be turned off with the power supply disconnected prior to cleaning, disinfecting and/or inspecting the device.

The turbine should be disinfected regularly to ensure the accuracy of measurements.

If the recommended disposable anti-bacterial filters are not used, each part which comes into contact with the patient should be disinfected prior to each test.

Cleaning and disinfecting

The goal of infection control is to prevent the transmission of infection to patients/subjects and staff during pulmonary function testing.

Cleaning and disinfecting instructions should be strictly followed to control infections and assure the safety of the patient. Aspiration of residue, particles and/or contaminated agents could be life threatening.

The recommendations in the following section are retrieved from Miller MR, Crapo R, Hankinson J, et al.: General considerations for lung function testing. Eur Respir J 2005; 26:153–162.

Prevention of infection transmission

Transmission to technicians

Prevention of infection transmission to technicians exposed to contaminated spirometer surfaces can be accomplished through proper hand washing and use of barrier devices, such as suitable gloves. To avoid technician exposure and cross-contamination, hands should be washed immediately after direct handling of mouthpieces, tubing, breathing valves or interior spirometer surfaces. Gloves should be worn when handling potentially contaminated equipment if the technician has any open cuts or sores on his/her hands. Hands should always be washed between patients.

Cross-contamination

To avoid cross-contamination, reusable mouthpieces, breathing tubes, valves and manifolds should be disinfected regularly. Mouthpieces, nose clips and any other equipment that comes into direct contact with mucosal surfaces should be disinfected, or, if disposable, discarded after each use.

Only the portion of the circuit through which rebreathing occurs must be decontaminated between patients, or, if disposable, discarded after each use. Disposable sensors, when appropriately used, avoid the need for decontamination of sensors and mouthpieces.

Tuberculosis

In settings where tubercolosis or other diseases that are spread by droplet nuclei are likely to be encountered, proper attention to environmental engineering controls, such as ventilation, air filtration or ultraviolet decontamination of air, should be used to prevent disease transmission.

Haemoptysis and oral lesions

Special precautions should be taken when testing patients with haemoptysis, open sores on the oral mucosa or bleeding gums. Tubing and breathing valves should be decontaminated before reuse, and internal spirometer surfaces should be decontaminated with accepted disinfectants for blood-transmissible agents.

Other known transmissible infectious diseases

Extra precautions should be taken for patients with known transmissible infectious diseases. Possible precautions include the following: 1) reserving equipment for the sole purpose of testing infected patients; 2) testing such patients at the end of the day to allow time for spirometer disassembly and disinfection; and 3) testing patients in their own rooms with adequate ventilation and appropriate protection for the technician.

Disposable in-line filters

These may be an effective and less expensive method of preventing equipment contamination.

The use of in-line filters does not eliminate the need for regular cleaning and decontamination of lung function equipment.

Other precautions and warnings

Please take the following precautions during the cleaning and disinfection activities:

1. The responsibility for handling, cleaning and decontaminating reusable medical devices should be assigned to trained, qualified individuals.

2. Appropriate protective clothing (gloves, masks, eye protection, gowns) will minimize the potential for personal exposure to blood borne and other disease-producing organisms.
3. Immediately separate and contain soiled reusable devices at the point of use and transport to the decontamination area so as to minimize risk of personal contact with contaminants.
4. A disinfectant solution is only effective if it can contact all surfaces of the items to be disinfected or sterilized.
5. Adequate ventilation is required in the disinfection area to evacuate the chemical vapors from glutaraldehyde (if used). Use lidded containers for the disinfectant solution when appropriate. The inhalation of fumes from disinfectant solutions or skin contact with liquid disinfectants can be hazardous to personnel.

> ***Warning:*** *Particular precautions should be taken when testing patients with high risk communicable diseases (i.e. Tuberculosis, Multidrug Resistant Staphylococcus infections, etc.). When such conditions are present the clinical need for performing the test should justify the risks.*

When performing the disinfection:

- Do not use alcohol or other liquids containing Gluteraldehyde on the exterior surface of the equipment.
- Do not use abrasive powders or glass cleaners containing alcohol or ammonia on the plexiglas component (mixing chamber or canopy) of the equipment.
- Do not steam autoclave any component other then rubber reusable masks (plastic adapter and clips should be removed).

> ***Warning:*** *Do not immerse any parts in liquid unless indicated (see following sections)*

Introduction

Decontamination is a multi-step process that includes preparation at point of use, thorough cleaning and rinsing and a microbicidal process. Thorough cleaning and rinsing are the first and most important steps in the reprocessing of any reusable medical device. Without thorough cleaning and rinsing it might not be possible to achieve high level disinfection or sterilization of the device. The purpose of cleaning and rinsing is to remove all adherent visible soil, to reduce the number of particulates and microorganisms, and to reduce the amount of pyrogenic and antigenic material. Any organic material, lubricants, or residual cleaning agents remaining on a device can inactivate liquid chemical disinfectants/sterilants as well as protect microorganisms from destruction.

The second step in decontamination is the microbicidal process which is defined as a process to provide a particular level of microbial lethality (kill). COSMED components are classified as "semi-critical" items which are devices that come into contact with intact mucous membranes. Semi-critical devices at a minimum require a high-level disinfection procedure. Sterilization is not absolutely essential.

COSMED components require complete or partial disassembly for cleaning and disinfection. It is the responsibility of the user (health care personnel) for ensuring that: the cleaning methods recommended can be duplicated in their environment, that appropriate tools, and replacement parts are available and that instructions are followed correctly.

Cleaning

> ***Note:*** *Please refer to additional, specific cleaning instructions for the turbine assembly below.*

Cleaning Agents/supplies

Mild detergents with a neutral pH (7) are recommended for cleaning. Use warm water (22°-43°c) with the mild detergent. To be effective, cleaning agents must assist in the removal of residual organic soil without damaging the device. cleaning agents should be used in the correct dilution/concentration and at the correct temperature in accordance with the cleaning agents manufacturer's directions.

Cleaning supplies are very basic, usually consisting of a surgical scrub brush, chenille pipe cleaners, cotton or foam tipped applicators, soft brushes, and soft cloths. Cleaning supplies should be cleaned and disinfected or sterilized daily.

Water Quality: tap water is acceptable for use in cleaning COSMED components.

COSMED components should be soaked and rinsed in tap water at 22°-43°C to prevent the coagulation of solid substances onto the device and thus facilitate the removal of debris.

Enzymatic detergents with a neutral pH (7) are recommended when processing difficult-to-clean items with dried-on matter. Soaking mask and valve components in an enzymatic detergent solution can effectively remove visible debris except for lubricants thus providing an acceptable alternative to manual cleaning. Rinsing is necessary to remove all traces of detergent and extraneous debris.

Standard cleaning procedure

These steps are common to all the cleaning procedures

Step 1 Preparation at Point of Use. The cleaning of reusable items begins soon after use. At the point of use, personnel wearing gloves and other protective attire separate disposable items or components from reusable items and discard them in appropriate receptacles. Soil is wiped from device surfaces with a moist sponge or towel. The soiled/contaminated items are then contained in a manner that will reduce the risk of personal exposure to pathogens. Items are usually placed in a basket, tray or rigid container for transportation to the processing area, usually transported in or on a cart, as hand carrying of soiled items is discouraged.

Step 2 Inspection. Inspect the items for damage at all stages of handling. If damage is detected on any of the components it should be identified and documented. Complete the disinfection/sterilization process and contact technical service for replacement.

Step 3 Presoak. Protective attire is required of personnel handling contaminated items. At the processing area soak or rinse the items in tap water 22°-43° C. Please note that rinse with flowing water is not possible on the turbine. If an enzyme product is required, soak for one to two minutes. Remove and examine, extend the soak time for components with dried-on matter, prolonged soaking of components may be detrimental, causing damage to the component surfaces. Refer to the detergent instructions for its usage and soak time.

Step 4 Disassembly. Disassemble the item (if necessary) according to the instructions reported in the corresponding section.

Step 5 Cleaning. Protective attire is required for personnel handling contaminated items. Manual cleaning must be done in a manner that protects personnel handling the devices from aerosolization and splashing of infectious material.

1. Manual cleaning of the items should be done under 22°-43°C water. Use a neutral pH (7) mild detergent. Water hardness, temperature and the type of soil affect the effectiveness of the detergents; the detergent manufacturer's instructions should be consulted. Use a small soft brush to scrub all parts. Abrasive cleaning compounds and implements can damage the items and should not be used. Additional cleaning supplies may be required to clean stubborn stains or hard-to-reach areas.
2. Items must be thoroughly rinsed with clean water to remove the detergent residuals and debris from the components. Use a flowing triple rinse cycle at a minimum with tap water. Please note that rinse with flowing water is not possible on the turbine.
3. Dry all components thoroughly using soft clean clothes or disposable paper towels.

Disinfection

The recommendations in this sections have been retrieved from:

William A. Rutala, Ph.D., M.P.H., David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC): Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

(http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf)

High-level disinfection is the recommended decontamination procedure for semi-critical devices.

Devices are classified semi-critical when they touches mucous membranes or broken skin. Examples of semi-critical devices are flexible endoscopes, laryngoscopes, endotracheal tubes, respiratory therapy and anesthesia equipment, diaphragm fitting rings, and other similar devices.

Preparing the disinfecting solution

The recommended disinfection solutions are as follows:

- Sodium hypochlorite 0.5% (5000 ppm) prepared fresh for use within 24 hours.
- Sodium hypochlorite 1% (10000 ppm) prepared fresh for use within 30 days.

The first solution can be prepared by adding 1 part household bleach (sodium hypochlorite 5.25%) to 9 parts water. The second solution can be prepared by adding 1 part household bleach to 4 parts water.

The turbine flowmeter

Guidelines recommend that the turbine should be cleaned and disinfected prior to every test to ensure accurate measurements and to comply with recommended sanitation measures as follow.

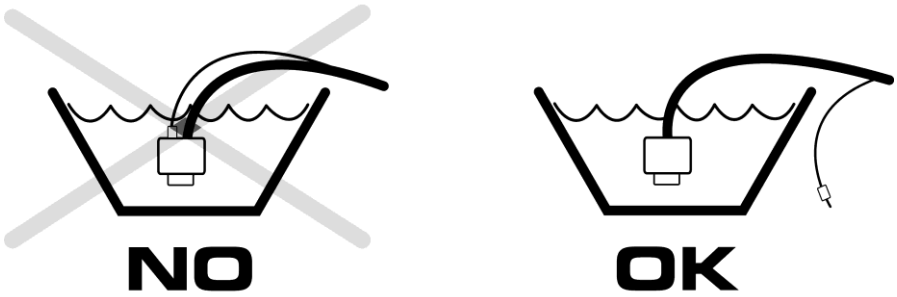
Cleaning the turbine

Follow the standard cleaning procedure reported above, paying attention to the following:

1. For rinsing, do not use flowing water, which may damage the turbine. Rinse the turbine in a vessel, filled of clean water, shaking gently to remove the disinfectant. Do not place the turbine under running water or move the turbine while submerged.
2. For cleaning and rinsing, do not wet the sampling line.
3. Use the brush (point 1 step 5) only for the external parts of the turbine, in order to avoid damages to the turbine blade.

Disinfecting the turbine

1. Disconnect the sampling tube from the reader.
2. Plunge the reader in a vessel containing the disinfectant solution for 20 minutes (see picture below) assuring that the sampling tube is not exposed to the solution (the optical flowmeter and cable are waterproof).



3. Rinse the turbine in a vessel filled with water and shake gently to remove the disinfectant (do not place the turbine under running water or move the turbine while submerged).
4. Allow the turbine to air dry (12 hours recommended depending on environmental conditions).
5. After cleaning the turbine, always calibrate prior to subsequent testing.

Precautions to take when cleaning, disinfecting and drying the turbine

- Do not expose the turbine to high heat or to a direct flow of water.
- Do not expose the sampling tube or the connector on the end of the cable to any liquids.
- Do not use alcoholic solutions to clean the turbine.

PNT X9

For cleaning and disinfecting the PNT X9 follow the same instructions as for the turbine, being careful to observe the following:

- Use distilled water for preparing the disinfectant solution, otherwise the calcium deposit could damage the flowmeter net
- Do not dry the PNT X9 with hot air which may damage the flowmeter net.

VO_2max mask and mixing chamber mask

The face masks, adapters and other components should be cleaned and disinfected prior to every test. Sterilization can optionally be performed on the rubber mask only. High level disinfection of mask and components ensures patient safety and minimizes the risk of infection.

Disassembling the mask

Remove the round black turbine adapter held within mask and the clips that hold the headcap in place.

Cleaning the mask

Follow the standard cleaning procedure reported above.

Disinfecting the mask

Step 1 Disinfection. Use only liquid glutaraldehyde disinfectant solutions approved as sterilants/disinfectants by the National Authority.

> ***Warnings***
>
> *The fumes of glutaraldehyde can irritate the mucous membranes of eyes, nose and throat.*
>
> *Some people develop allergic reactions to glutaraldehyde that can cause skin rashes, headaches and breathing difficulties.*
>
> *Containers of glutaraldehyde should be kept closed and in a well ventilated area.*
>
> *Gloves should be worn made of butyl or nitile rubber. Do not use latex rubber gloves.*
>
> *The concentration of glutaraldehyde in the air should not exceed 0.2 ppm.*
>
> *For emergency, safety or technical information about the glutaraldehyde solution contact the manifacturer.*

1. Determine the required soak temperature and time of the sterilant/disinfectant and assure that these requirements are met.
2. Activate the glutaraldehyde solution by mixing the components per the manufacturers instructions. Use the concentration testing devices sold by the manufacture to determine that the solution is above the minimum effective concentration.
3. Pour the activated glutaraldehyde solution into an appropriate sized basin.
4. Completely immerse the mask and components in the basin. Assure that all channels and cavities are filled with disinfectant and that no air pockets remain within the components.
5. Cover the disinfectant soaking basin with a tight fitting lid to minimize chemical vapor exposure.

Step 2 Rinsing. Adequate rinsing must follow disinfection to remove all traces of the toxic residues of the disinfectant left on the mask and components. Sterile water rinse is preferred over tap water. Tap water may contain a variety of micro-organisms which could recontaminate the components.

1. Rinse 1: Fill a basin with 7-8 liters of water (preferably sterile water). Place the mask and components into the basin and thoroughly rinse all the components for a minimum of one minute. Empty basin.
2. Rinse 2: Fill a basin with 7-8 liters of water (preferably sterile water). Place the components into the basin and thoroughly rinse all the components for a minimum of one minute. Empty basin.

Step 3 Hot water pasteurization: an alternative approach for disinfection (it can be performed in place of step 1 and 2). Completely immerse the device components in a hot water bath. All surfaces should be in direct contact with the hot water for 30 minutes at temperatures set between 71-76°C.

Step 4 Drying. To prevent the growth of waterborne organisms, the mask and components should be thoroughly dried prior to reassembly and storage.

1. Dry thoroughly using a soft cloth (preferably sterile) or disposable paper towels.

Step 5 Inspection. All components should be visually inspected for cleanliness, proper function and freedom of defects. Visual inspection provides evidence of thorough cleaning and proper functioning of all mask and components. Mask assemblies in poor working condition are hazardous to personnel and patients.

1. Visually inspect all components for cleanliness. If there are signs of residue from the detergent or disinfectant repeat the previous steps. If there are any signs of remaining stains or organic debris repeat the previous steps. If the cleaning and disinfection steps have been repeated with no improvement eliminating residual or stains etc, then dispose of the components and replace.
2. Visually inspect all components for defects. Check the rubber parts for tears, nicks, hardening or stiffening, deformation or distortion. Check the plastic parts for crazing, cracking or stripped threads. Any defective parts should be discarded and replaced.
3. Visually inspect all metal components for corrosion. Replace any metal components showing rust or chipped plated surfaces.

Sterilizing the mask

Sterilization of the silicone rubber face masks can be achieved with steam sterilization.

> ***Warning**: Sterilization can be performed on the rubber mask only. Do not apply sterilization on other parts.*

Type of Cycle: Gravity Displacement

Type of Load: Wrapped Method

Temperature: 132°-135°c

Cycle Time: 10-15 minutes

Special Notes:

1. Follow cleaning procedures as instructed prior to steam sterilization. Since the degree of sterility assurance depends on the amount of contamination of items to be sterilized, thorough cleaning procedures are essential.
2. All lubricants should be removed from components because this will interfere with steam contact.
3. Dry devices (components) reduce the potential for wet device packs after sterilization.
4. Sterilization container systems should be cleaned after each use.

Reassembling the mask and components

Reassemble mask and components.

Use appropriate personal protective clothing to assure that you do not recontaminate the components.

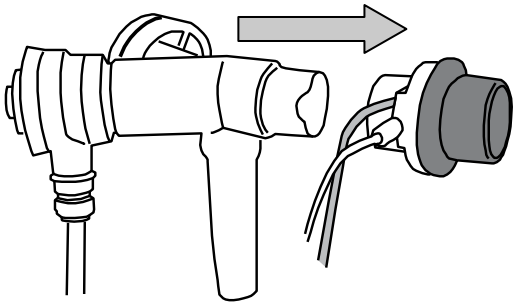
Cleaning the headcap assembly

Clean the head cap assembly (with strap clips) by hand washing with a mild detergent. Do not use bleach. Remove the head cap from the mask, leaving the strap clips attached to the straps. Machine or line dry. Do not iron the head cap assembly.

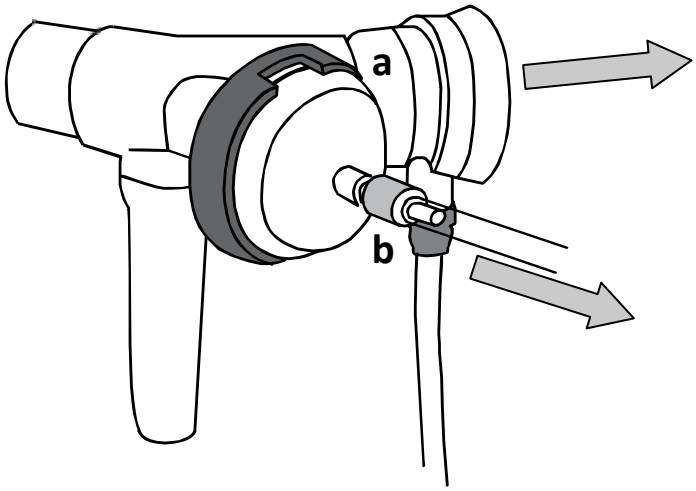
Breathing valve

The breathing valve should be cleaned and disinfected every day. Disinfection prior to every test is not necessary due to filtering during test maneuvers.

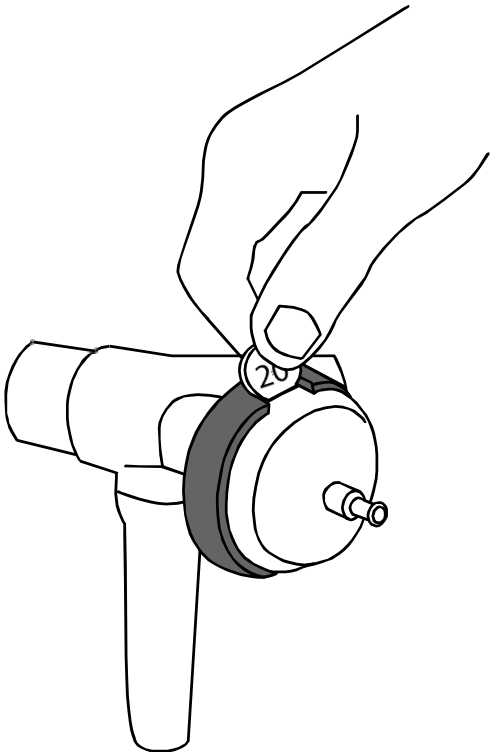
Disassembling the breathing valve



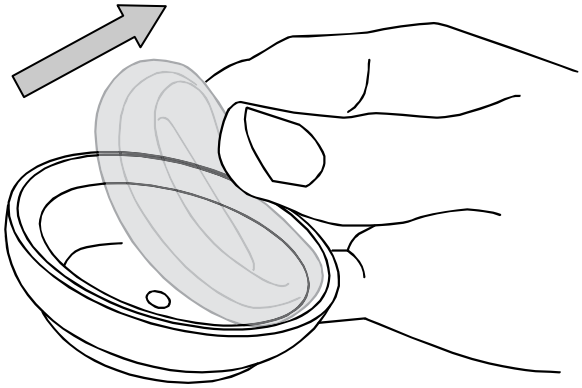
1. Remove the flowmeter from the breathing valve.



2. Remove the demand valve (a) from the breathing valve. Unscrew the tube (b).



3. Remove the cover on the rear of the breathing valve by means of a coin.



4. Remove the membrane paying attention to its orientation (must not be replaced upside down)

Cleaning the breathing valve

Follow the standard cleaning procedure reported above.

Do not immerse the demand valve in water.

Disinfecting the breathing valve

Disinfect the parts of the breathing valve, following the instructions for turbine disinfection.

> ***Note:*** *The demand valve cannot be disinfected.*

Reassembly the breathing valve

Re-assemble the breathing valve, repeating the steps described for disassembling in reverse order, paying attention to the orientation of the membrane.

Cleaning and disinfecting the RMR canopy hood and veil (option)

Cleaning hood and veil

The Canopy hood and the veil must be cleaned after every use by wiping with a soft cloth and a alcohol free solution.

Disinfecting hood and veil

Disinfect the parts following the instructions for turbine disinfection.

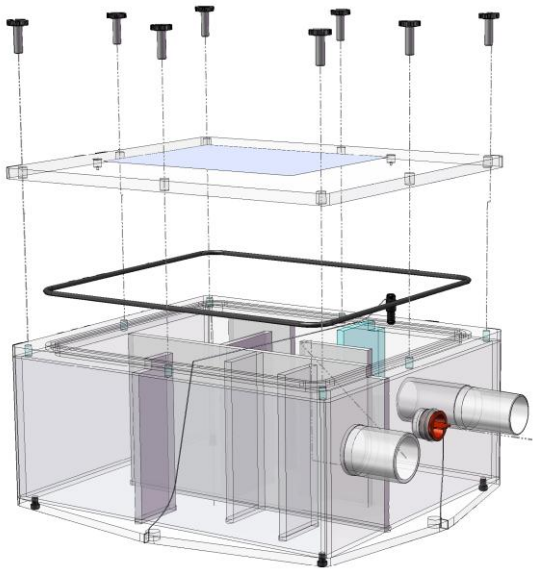
The mixing chamber (option): cleaning and disinfection

> ***Note:*** *Do not use alcohol, solvents or other abrasive substances for cleaning the mixing chamber.*

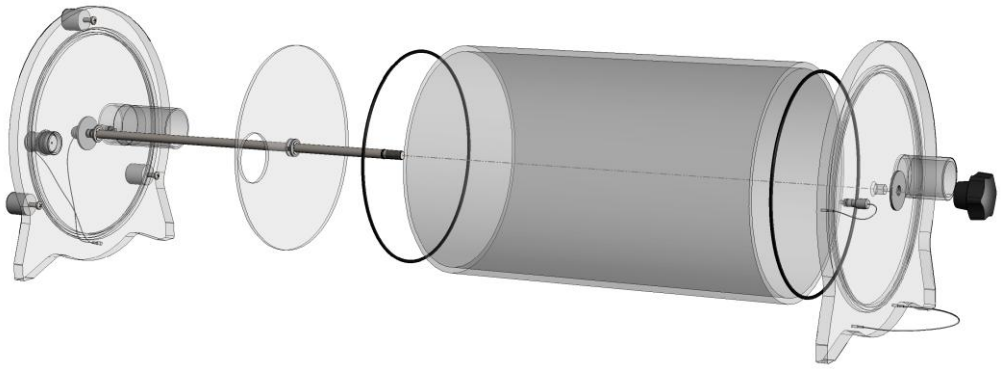
Disassembling the mixing chamber

Depending on the mixing chamber version (squared or rounded) the proper following instructions applies:

Squared mixing chamber: disassemble it by unscrewing the screws in the top cover



Rounded mixing chamber: disassemble it by unscrewing the black knob on the rear side.



Cleaning the mixing chamber

Follow the standard cleaning procedure reported above.

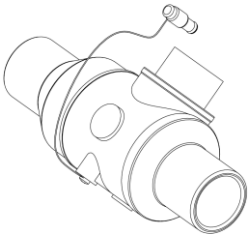
Disinfecting the mixing chamber

For disinfecting the mixing chamber, plunge each part in the disinfecting solution for 20 minutes (see turbine disinfection). Rinse and wipe.

Reassembling the mixing chamber.

After the cleaning, reassemble and carefully close the mixing chamber.

Two-way non rebreathing valve (mixing chamber option) cleaning and disinfection

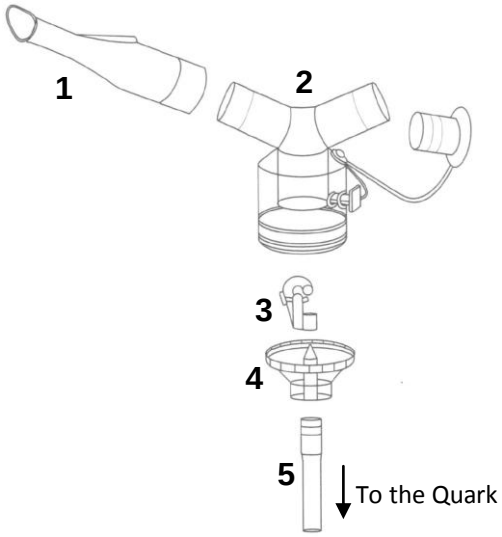


Refer to the indications reported in the sheet shipped together with the valve.

The valve must be disinfected after each usage on a patient.

Cleaning and disinfecting the dosimeter nebulizer

Cleaning and disinfecting should be performed after every patient.



1. Mouthpiece

2. Nebulizer (upper half)
3. Jet
4. Nebulizer (lower half, medicine reservoir)
5. Tubing

Routine cleaning

After every test:

1. Remove nebulizer tubing from nebulizer and from rear panel of Quark unit.
2. Remove mouthpiece.
3. Unscrew upper half of nebulizer from lower half and rinse all parts under warm water.

Daily:

1. Wash all components in soapy water. If jet is clogged, use a pin to re-open the aperture.
2. Rinse with warm tap water for 30 seconds, then soak in one part white vinegar to three parts hot water for 30 minutes.
3. Rinse with warm tap water and air dry.

Monthly:

1. Replace or clean tubing by following nebulizer cleaning instructions. To remove excess water from tubing, attach to the air source and allow air to pass through tubing until excess moisture is removed.

Disinfection

Disassemble as above.

Place all the parts in the disinfectant solution for at least 20 minutes. Let them dry in air.

The mouthpieces and the adapters must be disinfected only.

The nebulizer components may be sterilised by autoclaving or boiling. They may also be sterilised with any germicidal agent suitable for Lexan. Always prepare fresh solution for each cleaning cycle.

Sampling line maintenance (Permapure)

- Do not bend, squash or deform the sampling line. Any “kink” in the sample line will reduce the internal lumen of the line and affect accuracy of measurement.
- Do not keep the sampling line open to the atmosphere, particularly in crowded or smoky environments. Keep the sampling line in sealed plastic bag in a dark cool and dry place.
- If saliva enters the tube it should be replaced immediately.
- Periodically grease the O-ring on the connector to ease fitting to optical flowmeter.
- Replace the sampling line every 100 exercise tests or 200 PFT test or every 6 months. In any case, sampling line will become discoloured (brown) with age and may cause calibration to fail.

***Note**: ALWAYS replace sample line as the first step in troubleshooting a failed gas calibration.*

Inspections

The equipment requires inspections to be carried out to assure proper electrical and mechanical safety levels.

The inspections are recommended after extensive use of the equipment or after a long period of storage in unfavourable environmental conditions.

The insulation materials of cables, plugs and any other visible parts should also be inspected. The equipment should be turned off and adapters should be disconnected from the power supply when inspecting the materials.

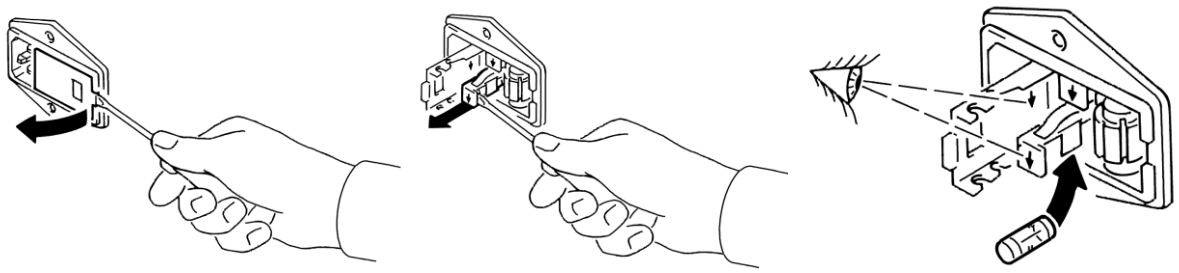
The turbine and breathing circuits also need to be inspected.

To inspect the turbine, perform the following procedure:

- Verify, by inspection, that the turbine axis fits correctly and the blade is fastened on the axis (you can lightly shake the turbine to note any anomalous movement).
- Assure that there are no torn or broken components in the breathing circuits.

Replace the fuses

The fuses can be replaced by performing the following procedure.



1. Open the power supply cover using a screwdriver as shown in the picture above.
2. Extract the fuse holder as shown above.
3. Replace the damaged fuse(s).

> ***Note**: Assure that the appropriate fuses are used when replacing previous fuses:*
> *A-680-024-125 (Time Lag Fuses 5x20 250V T1,25A)*

Appendix

Dichiarazione di conformità

Manufacturer: COSMED S.r.l.

Address: Via dei Piani di Monte Savello 37
00041 Pavona di Albano Laziale (RM)
ITALY

phone: +39-06-9315492
fax: +39-06-9314580

manufacturer of the following equipment:

Quark Spiro

Quark PFT

Quark CPET

declares under his sole responsibility that:

- the above listed equipment comply with the essential requirements of the Annex I of the Medical Device Directive 93/42/EEC;
- are classified in Class IIa;
- their design, manufacturing and final checks are performed according the Cosmed's Quality System, conform to ISO 9001:2008 and ISO13485:2003 Norms, certified by CERMET (certificates nr. 387-A and 387-M);
- are CE marked according to the Medical Device Directive 93/42/EEC and certified by CERMET (certificate nr. MED 9811).

The equipment conform with the following specifications:

Safety: IEC 60601-1

EMC: IEC 60601-1-2

CE
0476

Service - Warranty

Warranty and limitation of liability

COSMED provides a one year limited warranty from the date of the original sale of the product. COSMED products are guaranteed to be free from defect upon shipment. Liability for products covered by this warranty is limited to the replacement, repair or issuance of a credit for the cost of a defective product at the discretion of COSMED.

The following conditions must exist for the warranty to apply:

1) COSMED is promptly notified in writing by the buyer upon the discovery of defect.

2) The defective product is returned to COSMED with transportation charges prepaid by the buyer.

3) The defective product is received by COSMED no later than four weeks after the last day of the one year warranty period.

4) COSMED's examination of the defective product verifies that the defect was not caused by misuse, neglect, improper installation or an unauthorized repair or alteration.

If the product is manufactured by a third-party, the warranties provided by the third-party manufacturer will be the only ones available for the buyer. COSMED hereby disclaims any warranties or liabilities arising from defects or damages to and/or caused by products manufactured by a third-party. The buyer must obtain written authorization from COSMED prior to the repair or alteration of any COSMED products. Failure to obtain a written authorization will result in a void of the warranty.

The limited warranty shall not be enlarged, diminished or modified by the renderings of technical service from COSMED's agents or employees when the product is ordered or following the use of the product(s).

Return goods policy for warranty or non warranty repair

Products shipped to COSMED for repair are subject to the following conditions:

1. Products may only be returned upon receiving a receipt which includes the **Service Return Number (SRN)** from COSMED S.r.l.
2. The SRN report and packing list should be placed on the outside of the package.
3. Returned goods must be shipped with freight and insurance charges prepaid. **Collect shipments will not be accepted**.
4. The following list of products is not eligible for return unless proven defective.
   - Special order items.
   - Expendable products.
   - Products held over 30 days after the COSMED invoice date.
   - Used products not in the original shipping containers.
   - Goods which have been altered or abused in any way.
5. The following parts are not covered by warranty:
   - Consumables.
   - Fragile glass or plastic parts.
   - Rechargeable batteries.
   - Damages due to inappropriate use of the device.

Repair Service Policy

Goods returned to seller for non-warranty repair will be subject to conditions 1, 2, 3, 4.

Returned goods requiring customs documents (Pro-forma Invoice and Customs Paper) should comply with the Italian law.

- The shipment must qualify as a temporary export.
- Any goods returned to COSMED without customs papers will not be accepted.

For European Community members:

The Pro-Forma invoice should include the following:

- Number

- Description of the product
- Quantity
- Serial Number
- Value in €
- Number of parcel
- Gross weight
- Net weight
- Reason for repair

If repairs are needed, you may contact COSMED at the one of the following addresses:

COSMED S.r.l.

Via dei Piani di Monte Savello 37
P.O. Box 3
00041 Pavona di Albano - Rome, Italy
tel. +39 (06) 9315492
fax +39 (06) 9314580
E-mail: customersupport@cosmed.it

USA contact:

COSMED USA Inc

2211 North Elston, Suite 305
Chicago IL 60614 USA
Phone: +1 (773) 645-8113
Fax: +1 (773) 645-8116
email: usa.sales@cosmed.it

To ensure that you receive efficient technical service, please specify the nature of the problem as indicated on the assistance information form.

You should save the original packaging in case the need to ship the unit to a technical assistance centre should arise.

Privacy Information

Dear Customer,

We would like to inform you that your personal data is gathered and will be used by Cosmed Srl in conformity with the requirements of the Italian privacy law (Decreto Legislativo 196/2003). We believe it is important for you to acknowledge how your personal data is handled.

Personal data treatment and purposes

We request and process your personal data for the following purposes:

a) To place an order, register a product, request a service, answer a survey, enter a contest, allow communication with us and to supply necessary authorities with the required information.
b) To define your commercial profile.
c) To use your commercial profile for marketing or advertising purposes.
d) For necessary accounting procedures, such as emailing commercial invoices.
e) To provide information to the selected business partners needed to supply your service.

How your personal data is treated

Your personal data will be stored in an electronic format and protected against destruction, loss, unauthorized access or use not conforming to the purposes listed above.

Consent

The consent to treat your personal data is optional, but if denied COSMED cannot supply the appropriate services.

Holder of the personal data

Personal data is held by Cosmed Srl, Via dei Piani di Monte Savello 37, Pavona di Albano Laziale (RM).

Customer rights

In accordance with Art.7, you may:

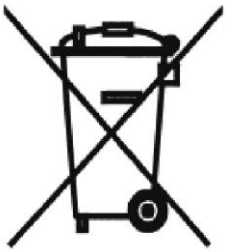
a) Obtain confirmation of the existence and sharing of your personal data.
b) Obtain information on the:
    - updating, correction or integration of your data;
    - deletion or transformation of your personal data;
c) Deny your consent to treatment of your personal data;

These rights can be exercised by a request in writing to the holder responsible for your personal data.

Disposing of electrical equipment

The device cannot be disposed as unsorted municipal waste. Electronic equipment must be collected separately according to the European Directive 2002/96/EEC. Otherwise it can cause dangerous consequences for the environment and human health.

The crossed-out wheeled bin means that the product must be taken to a separate collection when you wish to dispose of it.



Safety and conformity

Safety

IEC 60601-1/EN 60601-1;

The complete classification of the device is as follows:

- Class I with applied parts type B and BF
- Protection against water penetration: IPX1
- Non sterile device
- Device not suitable in the presence of flammable anaesthetics
- Continuous functioning equipment

EMC

The system meets the Standard IEC 60601-1-2.

Paramagnetic O_2 analyzer

The paramagnetic oxygen analyzer meets the requirements of the Standard IEC 68-2 (Basic Environmental Testing Procedures).

IEC 68-2-27: Shock

Peak acceleration:	100g (980 m/s^2)
Duration:	6msecs
Pulse shape:	Half sine

IEC 68-2-6: Sinusoidal vibration

Frequency range:	10Hz - 500Hz
Acceleration amplitude:	1g (9.8 m/s^2)
Type and duration of endurance:	10 sweep cycles in each axis

IEC 68-2-34: Random Vibration, Wide Band

Frequency range:	20Hz - 500Hz
Acceleration spectral density:	0.02 g^2/Hz
Duration:	9 mins

Quality Assurance

UNI EN ISO 9001:2008 (Registration n° 387-A Cermet)

UNI EN ISO 13485:2003 (Registration n° 387-M Cermet)

Medical Device Directive (CE mark)

MDD 93/42/EEC (Notified Body 0476).

Class IIa

Technical features

Flowmeter

	ID28 turbine	ID18 turbine	Flowsafe	X9
Type:	Bidirectional	Bidirectional	PNT Lilly	PNT Lilly
Diameter (int.):	28mm	18mm	-	28mm
Flow range:	0-16 l/s	0-8 l/s	0-14 l/s	0-14 l/s
Volume range:	0-300 l/min	0-50 l/min		
Resolution:	12 ml	3 ml	1 ml	1 ml
Accuracy:	± 2% or 20 ml/s	± 2% or 20 ml/s	± 2% or 20 ml/s	± 2% or 20 ml/s
Resistance:	<0.6 $cmH_2O/l/s$ @ 14 l/s	<0.7 $cmH_2O/l/s$ @ 3 l/s	<1 $cmH_2O/l/s$ @ 14 l/s	<1 $cmH_2O/l/s$ @ 14 l/s

O_2 analyzer

Type:	Paramagnetic
Response time:	120 ms
Range:	0-30% (0-100% FRC)
Accuracy:	±0.1%
Resolution:	0.01% (0.03% FRC)
Warm-up time:	5 min

CO_2 analyzer

Type:	Digital infrared
Response time:	100 ms
Range:	0-10%
Accuracy:	±0.1%
Resolution:	0.01%
Warm-up time:	10 min

CO analyzer

Type:	Infrared
Response time:	200 ms
Range:	0-0.35%
Accuracy:	±0.003%
Resolution:	0.001%
Warm-up time:	15 min

CH_4 analyser

Type:	Infrared
Response time:	200 ms
Range:	0-0.35%
Accuracy:	±0.003%
Resolution:	0.001%
Warm-up time:	15 min

Humidity absorber

Capillary of Nafion (Permapure ®)

Power Supply

Voltage:	100V-240V ±10%; 50/60Hz
Power consumption:	100VA

Environmental Sensors

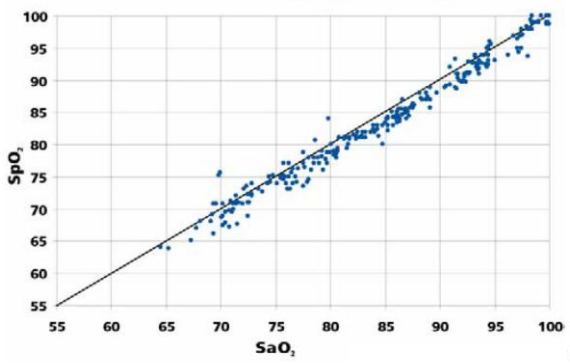
Temperature:	0-50°C
Barometer:	400-800 mmHg
Humidity:	0-100%

Dimension and Weight

Dimensions:	16x33x41 cm
Weight:	11 Kg (weight depends on the configuration)

Oximeter

A_{RMS} (70%-100%)	1.70
A_{RMS} (60%-70%)	2.16
A_{RMS} (70%-80%)	1.90
A_{RMS} (80%-90%)	1.80
A_{RMS} (90%-100%)	1.34



Accuracy specifications

FVC	±3.5% or 0.100L/s whichever is greater
FEV1	±3.5% or 0.100L/s whichever is greater
FEF25-75%	±5.5% or 0.250L/s whichever is greater
PEF	±7% or ±0.420 L/s whichever is greater
MVV	±10.5% or 20 L/min whichever is greater
FRC	±5%
DLCO	±5%
MIP/MEP	±3%
P0.1	±5% or 0.5 cmH_2O whichever is greater
SpO_2	±1%
Ve	±3%
RF	±3%
HR	±2 units
VO_2	±3%
VCO_2	±3%

Calculations references

VO_2 and VCO_2

"Energy Expenditure and Fuel Selection in Biological Systems: The Theory and Practice of Calculations Based on Indirect Calorimetry and Tracer Methods": M. Elia, G. Livesey, World Rev. Nutr. Diet. Basel, Karger, 1992, vol 70, pp 68-131.

"Nutritional Assessment in Critical Care, A Training Handbook": Donald C. Zavala

Anaerobic Threshold (modified V-Slope)

The intercept of the two slopes is defined as the VO2 above which VCO2 increases faster than VO2 without hyperventilation and can be selected automatically or manually by the software.

During incremental exercise above the Lactate Threshold, a net increase in lactic acid production results in an accelerated rate in VCO2 relative to VO2. When plotting these variables against each other a linear relationship is displayed. The slope of the lower component is slightly less than 1.0, whereas the upper component has a slope greater than 1.0. The intercept of these two slopes is the LT or AT point as measured by gas exchange.

The increase in VCO2 in excess of that derived from aerobic metabolism must be generated from the buffering of lactic acid. This is seen in all subjects exercising at work levels above their LT.

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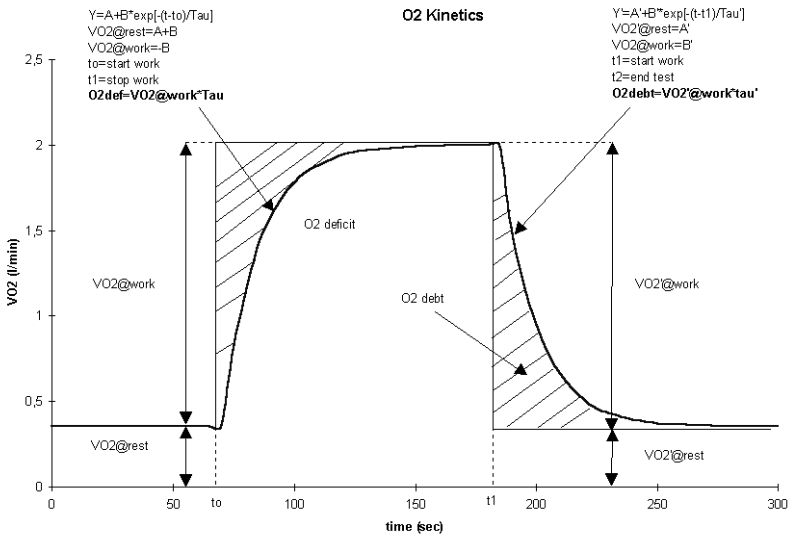
"Delayed Kinetics of VO2 in the Transition from prior Exercise. Evidence for O2 Transport Limitation of VO2 Kinetics: A Review"; R.L. Hughson and M.A. Morrissey, Int. J. Sports Med. 4 (1983) 31-39

ISO 8996: Ergonomics – Determination of metabolic heat production, 1990

The following picture displays how O_2 debt and O_2 deficit values are calculated.



Predicted values

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Standardized Lung Function Testing: Official Statement of the European Respiratory Society, The European Respiratory Journal Volume 6, Supplement 16, March 1993.

Compilation of reference values for lung function measurements in children: Ph. H. Quanjer, J. Stocks, G.Polgar, M. Wise, J. Karlberg, G. Borsboom; ERJ 1989, 2, Supp.4,184s-261s.

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Changes in the Normal Maximal Expiratory Flow-Volume Curve with Growth and Anging: J. Knudson, D. Lebowitz, J. Holdberg, B. Burrows; ARRD 1983; 127:725-734

ITS

Intermountain Thoracic Society: Clinical Pulmonary Function Testing, second edition (1984) pp 101, 144

LAM

A survey of ventilatory capacity in Chinese subjects in Hong Kong: Lam Kwok-Kwong, Pang Shing et Al. Annals of Human Biology, 1982, vol. 9, No. 5, 459-472.

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Spirometric reference values from a Mediterranean population: J. Roca, J. Sanchis, A. Agusti-Vidal, F. Segarra, D. Navajas. R. Rodriguez-Roisin, P. Casan, S. Sans. Bull. Eur. Physiopathol. Respir. 1986, 22, 217-224.

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Spirometric reference values from a sample of the general US population: John L. Hankinson, John. R. Odencrantz and Kathleen B. Fedan. Am J Respir Critr Care Med 1999, 159, 1798-187.

Pneumobil (Brazil)

Valores extraìdos do *Programa Pneumobil/Brasil* para a Tese de Doutoramento do Dr. Carlos Alberto de Castro Pereira. (Boehringer).

Gutierrez (Chile)

Gutierrez et Al. Reference values for Chile population

Knudson, Morris and Bass

The maximal Expiratory Flow-Volume curve: Knudson et al. ARRD Vol. 123, p. 659-664, 1981

Spirometric Standard for healthy non-smoking adults: ARRD Vol. 10-3, p. 57-67, 1971

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Neder JA, Andreoni S, Lerario MC, Nery LE. Reference values for lung function tests. II. Maximal respiratory pressures and voluntary ventilation. Braz J Med Biol Res 1999 ;32:719-27

Thai

Wanchai Dejsomritrutai; Khun Nanta Maranetra; Kittipong Maneechotesuwan; Nitipatana Chierakul; Jamsk Tscheikuna; Tasneeya Suthamsmai; Arth Nana; Benjamas Chuaychoo; Phunsup Wongsurakiat; Suchai Charoenratanakul; Wilawan Juengprasert; Chana Naruman: *Reference Spirometric Values for Healthy Lifetime Nonsmokers in Thailand,* J. Med. Assoc. May 2000 (83: 457-466)

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Reference Values for Residual Volume, Functional Residual Capacity and Total Lung Capacity - ATS workshop on Lung Volume measurements, official statement of the European Respiratory Society; J. Stocks, Ph. H. Quanjer: ERJ, 1995, 8, 492-506

Single Breath Oxygen Test

Buist SA, Ross BB: Quantitative Analysis of the Alveolar Plateau in the Diagnosis of Early Airway Obstruction. ARRD 108: 1081, 1973

Mansell A, Bryan C, Levison H: Airway Closure in Children. JAP 33: 711-714, 1972

Buist SA, Ross BB: Predicted Values for Closing Volumes Using a Modified Single Breath Test. ARRD 107: 744-751, 1973.

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Lombardi E, Sly PD, Concutelli G, et al. Reference values of interrupter respiratory resistance in healthy preschool white children. Thorax 2001; 56: 691-695.

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Leo F. Black, Robert E. Hyatt: Maximal Respiratory Pressures: Normal Values and Relationship to Age and Sex, American Review of Respiratory Disease, Volume 99, 1969

Vincken W, Ghezzo H & Cosio MG (1987). Maximal static respiratory pressures in adults: normal values and their relationship to determinants of respiratory function. Bull Eur Physiopathol Resp 23: 435-439.

Automatic diagnosis (algorithm)

Reference: "Lung Function Testing: selection of reference values and interpretative strategies", A.R.R.D., 144/ 1991:1202-1218.

LLN=Pred-0.674*SD (ATS, 50° percentile)

LLN=Pred-1.647*SD (ERS, 95° percentile)

LLN=Pred*0.8 (80%Pred)

Message interpretation	Criterion
Normal spirometry	FVC and FEV1/FVC > LLN
Obstructive abnormality (may be physiological)	% Pred FEV1 >= 100
Obstructive abnormality: mild	% Pred FEV1 < 100 and >= 70
Obstructive abnormality: moderate	% Pred FEV1 < 70 and >= 60
Obstructive abnormality: moderately severe	% Pred FEV1 < 60 and >= 50
Obstructive abnormality: severe	% Pred FEV1 < 50 and >= 34
Obstructive abnormality: very severe	% Pred FEV1 < 34
Restrictive abnormality: mild	FVC < LLN and % Pred FVC >= 70
Restrictive abnormality: moderate	% Pred FVC < 70 and >= 60
Restrictive abnormality: moderately severe	% Pred FVC < 60 and >= 50
Restrictive abnormality: severe	% Pred FVC < 50 and >= 34
Restrictive abnormality: very severe	% Pred FVC < 34

Quality Control Messages

Reference: Spirometry in the Lung Health Study: Methods and Quality Control, ARRD 1991; 143:1215-1223.

Message	Criterion
Start faster	VEXT >5% of the FVC and >150ml
Blast out harder	PEFT >120 msec
Avoid coughing	50% drop in the flow in first second.
Blow out longer	FET100% <6 sec.
Blow out more air	Flow >0.2l/s within 20 ml of FVC

Blow out harder	dPEF<10%
Take a deeper breath	dFVC<200ml and 5% best FVC
Blow out faster	dFEV1<200ml and 5% FEV1
That was a good test	No errors
FVC reproducible	Diff. 2 max FVC within 0.2 l
FEV1 reproducible	Diff. 2 max FEV1 within 0.2 l
PEF reproducible	Diff. 2 max PEF within 10 %
MVV time too short	MVV time less than 12 sec

References

Spirometry

ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING, Edited by V. Brusasco, R. Crapo and G. Viegi: Standardisation of spirometry, Eur Respir J 2005; 26: 319–338

Lung function", J.E. Cotes, Blackwell scientific publications

"Guidelines for Clinical Exercises Testing Laboratories", I.L. Pina, G.J. Balady, P. Hanson, A.J. Labovitz, D.W. Madonna, J. Myers. American Heart Association. 1995; 91, 912.

Dosimeter

Guidelines for Methacholine and Exercise Challenge Testing - 1999 Am. J. Respir. Crit. Care Med., Volume 161, Number 1, January 2000, 309-329 (Official Statement of the ATS adopted by the ATS Board of Directors, July 1999)

Lung Volumes

ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING, Edited by V. Brusasco, R. Crapo and G. Viegi: Standardisation of the measurement of lung volumes, Eur Respir J 2005; 26: 511-522

Single-Breath with Apnoea

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Single-Breath without Apnoea

Rest and Exercise Cardiac Output and Diffusing Capacity Assessed By a Single Slow Exhalation of Methane, Acetylene, and Carbon Monoxide; Ramage, Coleman and MacIntyre, CHEST 92, 1, July 1987

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P0.1

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P. J. Chowienczyk, C. P. Lawson, S. Iane, R. Johnson, N. Wilson, M. Silverman, G. M. Cochrane: “A flow interruption device for measurement of airway resistance”, European Respiratory Journal, 1991, 4, 623-626

G. Liistro, D. Stanescu, D. Rodenstein, C. Veriter: “Reassesment of interrupter, technique for measuring flow resistance in human”, J. Appl. Physiol., 67(3), 933-937, 1989.

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On line computer analysis and breath by breath graphical display of exercise function tests.”; Beaver, Wasserman, Whipp, JAP , 34(1):128-132, 1973

Measurement and analysis of gas exchange during exercise using a programmable calculator”; Sue, Hansen, Blais, Wasserman, JAP, 49(3), 1980:456-461

Principles of exercise testing and interpretation, 2nd edition”; Wasserman et Al, 1994

Clinical Exercise Testing, 3rd edition”, Jones 1988

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Energy Expenditure and Fuel Selection in Biological Systems: The Theory and Practice of Calculations Based on Indirect Calorimetry and Tracer Methods": M. Elia, G. Livesey, World Rev. Nutr. Diet. Basel, Karger, 1992, vol 70, pp 68-131

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Exercise Physiology - energy nutrition and human performance; William D. McArdle, Frank I. Katch, Victor L. Katch

General

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